EXHIBIT DX36

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

In re Bair Hugger	Forced	Air	Warming
Products Liability	Litigati	on	

MDL No. 15-2666 (JNE/FLN)

This Document Relates to All Actions

EXPERT REPORT OF

SAID ELGHOBASHI, M.SC., PH.D., D.SC.

Attached as exhibit 1 is my report, Effect of Heated-Air Blanket on the Dispersion of Squames in an Operating Room, Dated March 23, 2017

Attached as exbibit 2 is a Summary of Opinions.

Attached as exhibit 3 is my professional Resume.

I have not previously testified in trial or deposition.

My hourly charge for professional services is \$800.00

Date: March 29, 2017

Said Elghobashi, M.Sc., Ph.D., D.Sc.

A Elghobestin

Exhibit 1

Effect of Heated-Air Blanket on the Dispersion of Squames in an Operating Room

Said Elghobashi

Mechanical and Aerospace Engineering
The Henri Samueli School of Engineering
4220 Engineering Gateway
University of California, Irvine
Irvine, CA 92697-3975
Phone: (949) 824-6131
Email: selghoba@uci.edu

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Effect of Heated-Air Blanket on the Dispersion of Squames in an Operating Room

Abstract

A large-eddy simulation (LES) of the interaction between the ventilation air flow and forced hot air from a blower is performed to investigate the effect of hot air on dispersion of squames in a realistic operating room (OR) consisting of an operating table (OT), side tables, surgical lamps, medical staff, and a patient. Two cases with blower-off and blower-on are calculated together with Lagrangian trajectories of 3 million squames initially placed on the floor surrounding the OT. The squames particles are assumed as spheres of size 10 microns and the drag, lift and buoyancy forces are considered in calculating their instantaneous motion. It is shown that with the blower-off, squames are quickly transported by the ventilation air away from the table and towards the exit grilles. However, with the hot air blower turned on, the ventilation air flow above and below the OT is disrupted significantly. The rising thermal plumes from the hot blower air drag the squames above the OT and the side tables and then they are blown downwards toward the surgical site by the ventilation air from the ceiling. Temporal history of number of squames particles reaching four imaginary boxes surrounding the side tables, the OT, and the patient's knee shows that several particles reach these boxes with the blower turned on. The study shows that LES is necessary to accurately capture the mixing and transport in a turbulent flow and predict the dispersion of squames in an OR.

1 Introduction

- ² Microbial skin colonizers, such as Staphylococcus aureus, have been known as a major cause of
- surgical site infections in operating rooms (Noble, 1975; Clark & de Calcina-Goff, 2009; Wood
- 4 et al., 2014). These bacteria typically colonize on human skin cells or squames which are routinely
- shed by humans, roughly about 10⁷ particles per day (Noble, 1975). The squame particle size ranges
- 6 over 4–20 μm of equivalent diameter (Noble et al., 1963; Lees & Brighton, 1972).
- Reduction of post-operative surgical site infections has been linked to two main factors: (i)
- s ultra-clean ventilation (UCV) systems, and (ii) perioperative patient warming (Ng et al., 2006; Legg
- 9 et al., 2012; Wood et al., 2014). Ultra-clean ventilation aims to reduce the quantity of airborne
- bacteria in the operating room (OR) and most importantly near the surgical site. This is typically
- achieved by the constant delivery of highly filtered ultra-clean air with a downward uniform yelocity
- of 0.3-0.5 m/s (McGovern et al., 2011). The UCV performance depends critically on volumetric
- airflow, proper temperature gradients, use of uniform downward flowing ventilation air, potentially
- in the laminar regime (Memarzadeh & Manning, 2002; Pereira & Tribess, 2005). Surgeons and
- other medical equipment within the operating room (surgical lights, tables, patient, computers, etc.),
- motion of surgeon's arms and their bending motion (Chow & Wang, 2012) can disrupt this air flow

and create wakes, flow unsteadiness, and turbulence, thereby increasing the amount of cfu in the OR.

Perioperative patient warming is the other important clinical practice to prevent inadvertent sur-19 gical hypothermia, wherein the core temperature of the patient drops below 36°C. Preventing inadvertent perioperative hypothermia has several benefits that include reduced operative blood loss, reduced duration of surgery, improved wound healing, reduced wound infections, reduction in post-22 operative ulcers, reduced duration of hospital stay, and increased survival rates (Wood et al., 2014; 23 Ng et al., 2006; Legg et al., 2012). Monitoring and maintaining body temperature during surgery is therefore an accepted and required practice. Warttig et al. (2014) review different methods used to 25 combat inadvertent perioperative hypothermia. These include use of warm cotton blankets, reflective blankets, warmed intravenous and irrigation solutions, circulating warm water mattresses, a reusable electric blanket, an electric heating pad, and forced-air warmers (Kellam et al., 2013; Austin, 2015). Of these, active warming using forced air warming (FAW) devices, and passive warming based on the use of reflective blankets, are the two main techniques used to keep the patient's body warm and prevent hypothermia. Although passive heating techniques may show similar effectiveness as the FAW devices, the latter have been used for over two decades due to their efficacy in maintaining patient's core body temperature. These techniques use forced convection to increase the skin 33 temperature and the total body heat content. These devices contain a blower (such as 3MTM Bair 34 HuggerTM) that extracts the room temperature air through an air-intake filter heats the air using a heating coil, and vents the air into the sterile field adjacent to the operative site (Albrecht et al., 2011; Leaper et al., 2009; Wood et al., 2014). The filtered and warm air flows through a connecting hose into blankets made of plastic and exits the blankets through tiny holes over the patient's skin. However, this forced warm air has the potential to generate and mobilize airborne contamination in the operating room. 40

A number of studies have examined at the safety of forced-air warming, and whether FAWs
can affect surgical site infections through mobilized airborne contamination. FAWs can potentially
lead to surgical site contamination in two ways: (i) direct contamination of the air from the blowers
that reaches the patient's body, and (ii) disruption of the ultra-clean ventilation air by the thermal
plumes and turbulence. The former risk can potentially be reduced by using intake filers that are
HEPA-rated and show high filtration efficiency. The latter has been studied extensively as reviewed

by Wood *et al.* (2014). It is hypothesized that the temperature gradients and resultant thermal plumes
created by the FAW devices could disrupt the benefits of UCV flow, that is designed to be uniform
and downwards. The interaction between the FAW and UCV flows may lead to increased surgical
site infections (SSI).

McGovern et al. (2011); Legg et al. (2012) have shown that temperature gradients and excess 51 heat created by FAW devices can transport air from the unsterilized floor level to the surgical site, thus increasing the potential risk of SSIs. Moretti et al. (2009) measured an increase in the bacterial 53 load when FAWs were used. Lack of flow visualization is the main drawback of these studies as 54 it does not provide information about whether the particles came from the floor or from the FAW blower. Legg et al. (2012); Sessler et al. (2011) used smoke particle visualization to understand the 56 source of these particles near the surgical site comparing cases with no warming, FAW, and radiant 57 warming. Although they found that FAW increased the particle count with blower turned on (almost 58 10-fold increase), they also showed that the uniform, laminar flow from the ultra-clean ventilation reduced the effect of particles by limiting their numbers near the surgical site. 60

It is clear from the available literature that the interaction between the UCV flow and the rising 61 plumes from the forced-air warming devices plays a critical role in deciding whether FAWs indeed can lead to increased number of particles near the surgical site. However, there have not been de-63 tailed experimental measurements of flow patterns in the OR setting with the FAW blower turned on. 64 Recently, McNeill et al. (2012, 2013) conducted particle-image velocimetry (PIV) measurements 65 to understand the flow pattern in an OR with the ultra-clean ventilation system. This study, however, did not investigate the effect of FAW blower. McNeill et al. (2013) also made detailed measurements of temperature fields on surgeon's and patient's body to be used for computational modeling. Although the above PIV was able to visualize and measure the flow field, it was limited to planar data (2D PIV) and thus a full three-dimensional data are not available for the OR. Nevertheless, some useful information on the flow unsteadiness, turbulence within the room was obtained from 71 the McNeill et al. (2013) study. 72

The only other way to characterize the flow field in an OR with and without FAW blowers, is to use computational fluid dynamics (CFD) modeling in three-dimensions. This, however, is a difficult task due to the size and complexity of the domain involving medical equipment, staff, computers, etc. There are only few CFD studies in the literature that used Reynolds-averaged Navier

Stokes (RANS) models (Memarzadeh & Manning, 2002; Memarzadeh, 2003; Chow & Wang, 2012), wherein only the time-averaged velocity field is computed. All information about the turbulence and velocity fluctuations is completely modeled. As is shown later (section 3), RANS approach is not 79 predictive, since the instantaneous velocity field needed for calculating the trajectories of squames is BO not directly computed. Thus, RANS is incapable of accurately predicting the locations of squames at any time in the OR. Memarzadeh & Manning (2002); Memarzadeh (2003) investigated the effect of various UCV inlet flow conditions on the transport of squames particles in an OR. They considered 83 a realistic OR with medical staff, equipment, surgical lamps, etc. and accounted for the thermal plumes created by heat radiated from various sources. However, they used a RANS model coupled with a Lagrangian particle-tracking of around 4000 representative particles. Their study did not include the FAW blower discharge. They showed that use of a uniform inlet flow with laminar conditions is better for reducing the number of particles near the surgical site. In addition, they found that the thermal plume created by the hot surface of the surgical site prevented particles from reaching the site. They showed that roughly 2-5% of particles reach the surgical site, provided they are originated very close, about 1.3cm above the site. Particles originating from locations away from the surgery did not have a statistically significant probability of reaching the surgical site. As is discussed later in section 3, RANS model cannot compute the instantaneous velocity field needed to accurately calculate the forces on particles, and particle trajectories. 94

Chow & Wang (2012) investigated the ultra-clean ventilation flow and its effect on bacteria-carrying particles in an OR using a RANS model as well. They simulated the bacteria particles as a non-inertial pollutant, wherein an Eulerian transport equation for the concentration of the bacteria is calculated. In addition, they considered periodic bending movement of one of the surgeons performing the operation. They found that if the surgical staff stands upright (no bending), the UCV flow keeps the bacteria concentration very low (< 1 cfu/m³) near the surgical site. However, with the surgeon's bending motion included, they showed that this concentration increased to larger than the recommended value (10 cfu/m³).

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All of the above computational studies are based on RANS modeling and did not include the

¹It should be noted that the literature uses the terminology 'laminar flow' for the ultra-clean ventilation flow. Based on the standard values of air changes per hour (ACH) for an OR (25 per hour), the inlet grille sizes, and properties of air, the flow Reynolds numbers are much larger than 2000, a critical value beyond which turbulence occurs in a duct. The inlet grille flow, thus is not typically laminar. Although the level of turbulence in the inlet flow is not large (< 10%), the flow contains velocity fluctuations and is unsteady.

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FAW blower system together with a blanket cover above the patient. In order to assess the interaction between UCV and FAW blower, a systematic, predictive simulation is needed. Largeeddy simulation (LES) is a numerical technique that involves computing the properties of the large, energy-containing eddies of turbulence accurately, without any user adjustable tuning parameters, and models only the more homogeneous, small scales of turbulence (Pope, 2000; Piomelli, 2014). This technique provides the instantaneous three-dimensional velocity, temperature, and pressure fields and has been shown to be far more accurate than the RANS model. Section 3 outlines the differences between LES and RANS in detail. In addition, since the time dependent, three-dimensional velocity field is available in LES, then the forces on particles and their trajectories can be calculated accurately (Apte et al., 2003b; Ham et al., 2003; Apte et al., 2009; Moin & Apte, 2006; Mahesh et al., 2006). The only challenge with this technique is that it is computationally intensive and requires fine grid resolutions and small time-steps to capture the large-scales of turbulence. Recent advances made in algorithmic developments for LES on arbitrary shaped, unstructured grids (Mahesh et al., 2004; Ham et al., 2003; Moin & Apte, 2006; Mahesh et al., 2006; Ham & Iaccarino, 2004) have facilitated application of LES to more realistic problems involving complex geometries and flow conditions. These advances have been successfully applied to turbulent, reacting flows in a gas-turbine combustion chamber and has led the gas-turbine industry to switch from RANS to the predictive LES technique in their design cycle (Moin & Apte, 2006; Mahesh et al., 2006; Apte et al., 2009).

LES applied to operating rooms with medical staff and other instruments is still challenging, owing to the size of the room and the complexity of the geometries involved. At the time of writing this report, only one LES study has been performed for an operating room by Saarinen *et al.* (2015). They studied the escape of air into an isolation room during opening and closing of a door and passage of a human figure. They used passive smoke visualizations to compute the volume flux of air when a door is opened. Although this study had some complex geometry (a human figure), it did not have the intricacies of the OR table, surgeons, patient and other medical equipment, nor it computer the dispersion of squames in the OR. Nevertheless, it showed that LES can accurately predict such flows through validation with experimental observations.

The main goal of the work reported here is to use large-eddy simulation to compute the interaction of the OR ultra-clean ventilation air flow and the flow created by forced air warming system (such as 3MTM Bair HuggerTM) and investigate their impact on the dispersion of squames.

Specifically, computations are conducted for the cases with blower-off and blower-on, including the

Lagrangian tracking of inertial squame particles, starting from the operating room floor, to prove

whether the FAW system and the resultant thermal plumes play a role in transporting squame parti
cles to the surgical site.

The rest of the report is arranged as follows. In section 2, details of the operating room geometry and CAD model are described. This includes the OR dimensions, the surgical lamps, four medical staff, an operating room table, two side tables, the blower, and the patient undergoing knee surgery. The numerical approach is described in section 3. This includes a detailed discussion of LES and RANS, the governing equations used for LES, the computational grid, and the boundary conditions. The numerical algorithm used is briefly summarized in section 3.5. This is followed by detailed description of the results in section 4 on flow field, particle trajectories and particle counts that reach the surgical site and other key regions of interest. Finally, the findings are summarized in section 5.

2 Operating Room Geometry and CAD Model

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The operating room CAD (computer aided design) model was created using Ansys® SpaceClaim
Direct ModelerTM (ANSYS, Inc., Canonsburg, PA, USA). The CAD model replicated a realistic
operating room (OR) depicting a knee surgery being performed on a patient. An original baseline
CAD model was obtained from M/E Engineering P.C. (Straub, 2016) and was further modified
to incorporate the measured dimensions of the inlet air grilles and the surgical drape as shown
below. Figure 1a shows the OR dimensions used to create the CAD model. The length, width
and height of the room are 7.32m, 7.01m and 3.18m, respectively. These dimensions are from 3M
video at: https://www.youtube.com/watch?v=QhzeInWIJ54. Figure 1b shows a close-up view of the
surgeon's hands extended over the patient's knee mimicking a real world operating procedure.

The CAD model also includes several objects that are usually present in a real OR. Typically, there can be several combinations of such objects, but for this study the following objects were included in the model. These are shown in a top view in figure 2 and include: (i) OR Table; (ii) OR drape; (iii) patient's body under the drape with knee exposed; (iv) four surgeons (two of the surgeons have extended hands and two have hands down), (iv) two side tables, (v) two surgical lamps, (vi)

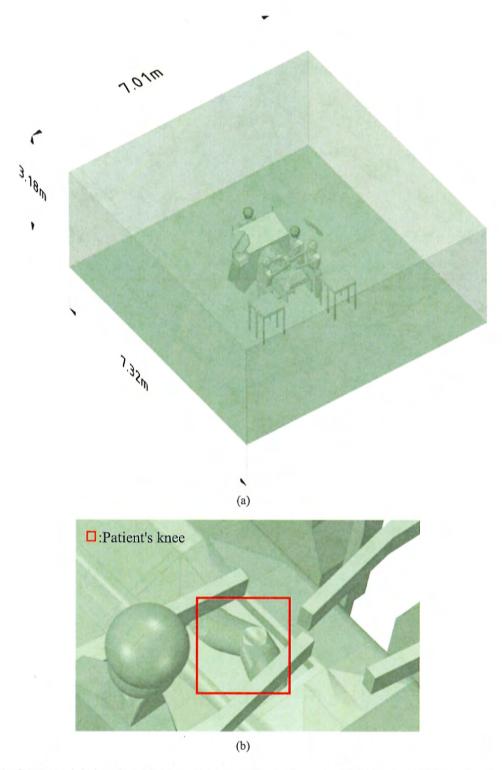


Figure 1: CAD model showing (a) operating room dimensions, and (b) closeup of the patient's knee.

3MTM Bair HuggerTM blower unit (partly visible near the top left corner under the drape).

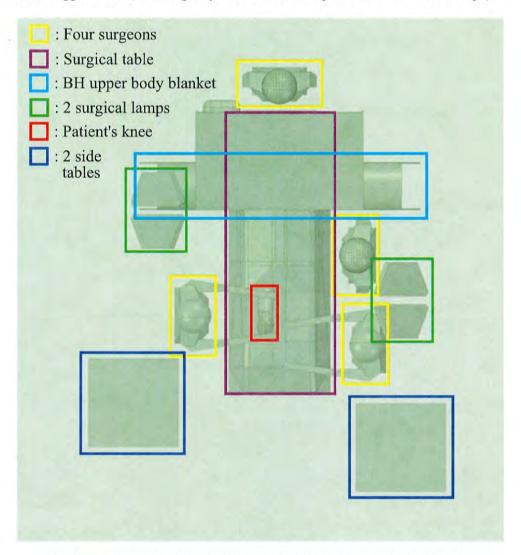


Figure 2: Close-up view of various objects included in the CAD model.

Figure 3 shows a side view of the OR table together with a few key dimensions. The bottom of the OR table is 0.94m above the floor of the room. The drape on the OR table covering the patient's torso is suspended 0.52m above the floor. The 3MTM Bair HuggerTM blower unit is also seen in the bottom right side of the figure.

The drape design from the base CAD model was modified to better represent the drape layout in a real OR room. The modifications mainly focused on using accurate dimensions and shape of the drape near the front end based on an actual picture taken in an OR room as shown in figure 4b. A corresponding CAD model used in the present study is shown in figure 4a. For the CAD model, the

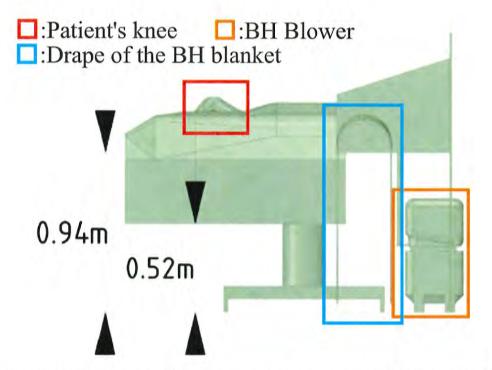


Figure 3: Side view of the OR table with some key dimensions. The 3MTM Bair HuggerTM blower unit is clearly visible on the bottom ride side.

front end of the drape was designed to mimic the shape obtained by dimensions A, D, C, E in figure
4a. The dimensions in the CAD model are given in both metric and imperial units (in brackets) in
this figure to facilitate direct comparison with the real picture on the right. The distance between the
vertical bars holding the drape, denoted by dimension F in Figure 4b, was also implemented in the
CAD model.

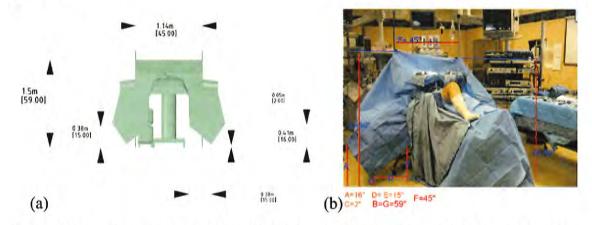


Figure 4: Drape dimensions and configuration: (a) model developed to match the drape dimensions, (b) actual drape picture in an OR room. The dimensions are shown in both metric and imperial units (in brackets).

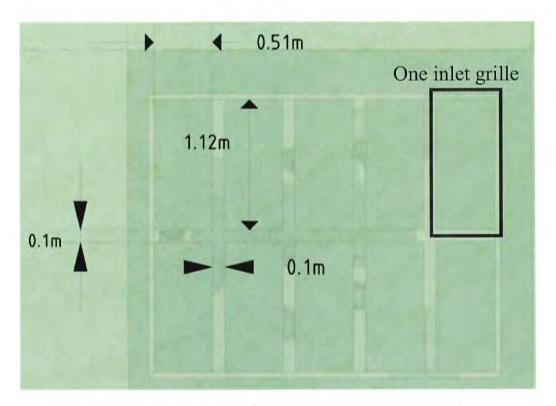


Figure 5: Ten inlet grills to supply clean filtered air into the OR.

The CAD model included ten inlet grilles (figure 5) for supplying clean filtered air to the OR.
Each inlet grille is 0.51m in width and 1.12m in length. All ten grilles are of the same size. There is
a gap of 0.1m between the neighboring grilles at all sides.

There are four exhaust (or outlet) vents, two on each side wall. Figure 6 shows two outlet grilles (with the other two outlets located on the opposite wall). Each outlet grille is 0.71m in width and 0.71m in length.

3 Numerical Simulation

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A state-of-the art, fully parallel, unstructured, co-located grid flow solver based on principles of kinetic energy conservation for large-eddy simulation (Moin & Apte, 2006) of turbulent flow in the limit of zero-Mach numbers is used in this study. This solver is MPI-based, uses algebraic multigrid for the pressure Poisson equation, and third-order WENO-based scheme for transport of scalar fields such as temperature. It has been thoroughly validated for a number of different particle-laden turbulent flows (Apte et al., 2003b,a, 2008a, 2009, 2008b) including swirling turbulent flow

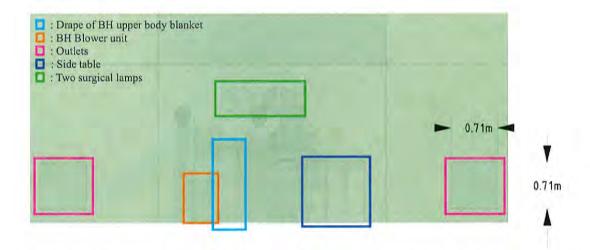


Figure 6: Outlet (exhaust) grilles for air exit from the room. Out of the four outlets in the CAD model, only two are visible in the picture. The other two outlets are on the the opposite wall.

in a co-axial combustor, turbulent reacting flow, as well as spray combustion in a realistic Pratt and
Whitney gas-turbine combustion chamber (Moin & Apte, 2006; Mahesh *et al.*, 2006).

3.1 Large-eddy Simulation (LES): Introduction and Need

The physics of turbulent air flow containing heated buoyant plumes and laden with inertial particles in a real-life operating room is highly complex. Simulating such flows with predictive capability is difficult as turbulence, by nature, consists of a broad range of length- and time-scales and is inherently three-dimensional. In addition, the geometry of a realistic operating room consists of complex surfaces involving surgeons, operating table, surgical lights, patient, among other. If a probe measures the velocity at a certain location in such a flow, the velocity signal will show a broad range of frequencies and fluctuations around a mean. A typical kinetic energy spectrum obtained via Fourier transform of turbulent velocity field is shown in figure 7, especially for moderate to large Reynolds numbers. The spectrum is broad-band with large amount of kinetic energy per wavenumber present at large scales (small wavenumbers) and small amount of energy present at smaller scales (larger wavenumbers). There also exists an inertial range, scales in this regime simply transfer the energy from larger scales to smaller scales through a process commonly known as the energy cascade (Pope, 2000). As the Reynolds number increases, this spectrum is known to broaden. The largest scales (£) of motion are typically confined by the size of the domain (for example, size of the inlet jet

or size of the room). However, as the Reynolds number increases, the smallest scales of motion (known as the Kolmogorov scales, η) are reduced until the kinetic energy is dissipated into internal energy by the viscous effects. Owing to this broad range of scales, prediction of turbulent flows at large Reynolds numbers becomes difficult and is only possible if the behavior of all scales of motion is captured properly.

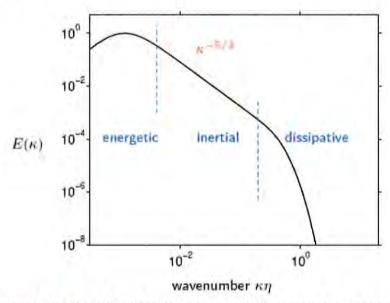


Figure 7: Schematic of a turbulence kinetic energy spectrum showing energy per wavenumber as a function of the wavenumber (Pope, 2000). The inertial range of scales is indicated by the -5/3 slope line that separates the energetic large scales and dissipative small scales of turbulence. In DNS, the grid resolution is fine enough to capture all scales, whereas in LES, the grid resolution is coarser (typically 10 times the Kolmogorov length scale), placing the grid cut-off somewhere in the inertial range.

Three basic approaches can be identified for prediction of turbulent flows: (i) direct numerical simulation (DNS), (ii) Reynolds averaged Navier-Stokes (RANS) modeling, and (iii) large-eddy simulation (LES), and are briefly described below.

DNS: In direct numerical simulation (DNS), the Navier-Stokes equations are solved on a computational grid that is fine enough, in space and time, to directly capture *all* the scales associated with the fluid flow motion without requiring any additional models. This means that the computational grid in three-dimensions is small enough to capture the smallest scales of turbulence and the time-step is small enough to capture the smallest time-scale associated with the flow. Using scaling arguments based on the Kolmogorov hypotheses (Tennekes & Lumley, 1972; Pope, 2000) used in the theory of turbulence, it can be shown that for a simple homogeneous, isotropic turbulence in a box, the grid resolution requirement ($\Delta \sim \mathcal{L}/\eta$; where \mathcal{L} is the size of the large, energy-containing

eddies) for DNS varies as $Re_{\mathscr{L}}^{3/4}$, where $Re_{\mathscr{L}}$ is the Reynolds number based on \mathscr{L} and the velocity fluctuations u, in one coordinate. Hence, the total number of mesh points needed in three-dimensions varies as $Re_{\mathscr{L}}^{9/4}$. A simple isotropic turbulence in a box at $Re_{\mathscr{L}} = 2000$, would require computational grid containing about 27M control volumes (= 300^3). In addition, based on numerical constraints of a computational solver, for a fluid flow of unit velocity, the grid spacings (Δ) and the time-steps (Δt) are roughly of the same order of magnitude (CFL = $u\Delta t/\Delta \sim 1$) and thus the spatio-temporal resolution will require a computational power that increases as $Re_{\mathscr{L}}^3$. Owing to the grid requirements and associated computational costs, DNS is not practical for realistic engineering applications and is restricted to canonical geometries and flow problems to study the fundamentals of turbulence (Moin & Mahesh, 1998).

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RANS: According to the above discussion, the computation of practical turbulent flows relies predominantly on the Reynolds-averaged Navier-Stokes (RANS) equations approach. In RANS, the governing equations are averaged in time to obtain equations for the time-averaged velocity field, $\overline{u}(\mathbf{x})$. Thus, in this approach, only the mean velocity field that varies in space is obtained, and all information about the time-dependent fluctuations of the velocity field around the mean flow is lost. Because the momentum equations are non-linear (owing to the inertial, advective terms), a time-average of the non-linear term creates additional quantities that are unknown, giving rise to the classical closure problem of turbulence (Tennekes & Lumley, 1972; Pope, 2000). In order to evaluate these terms, models are introduced wherein the effect of the entire spectrum of turbulence (involving the large, inertial, and small scales shown in Figure 7) is completely modeled. This is usually done by introducing two additional transport equations for the turbulence kinetic energy (k) and the kinetic energy dissipation rate (ε) , giving rise to the $k-\varepsilon$ model. It should be noted that the transport equations for k and ε also contain a large number of unknown, unclosed terms which also need to be modeled. The model constants are obtained by fitting the RANS predictions to the experimental data on simple, canonical flows such as wall bounded channel flow, isotropic turbulence, or free-shear flows. Because these models and model constants are not universal, using them for a complex flow such as air circulation in an operating room, invariably provides inaccurate results. Experimental data is necessary to adjust the model constants and thus the RANS models are not predictive. However, since only the time-averaged velocity field is calculated, the RANS approach is computationally the least expensive because it does not require the spatio-temporal resolution

necessary for the DNS studies. There are modified approaches, wherein the large-time scale variations are captured by solving the RANS equations in an unsteady manner. These unsteady-RANS simulations also suffer from the same hypotheses and models used for the basic RANS and their predictive capability is also poor.

LES: The energy spectrum (figure 7) shows that a substantial portion of the turbulence kinetic energy (TKE) is contained in the large-scales, known as the energy containing scales. In LES, only the contribution of the large, energetic structures to momentum and energy transfer is computed exactly, and the effect of the small scales, also termed as unresolved or subgrid scales, of turbulence is modeled. Since the small scales tend to be more homogeneous, and less affected by the domain boundary conditions as compared to the large eddies, then the subgrid closure models used in LES are universal and can be applied to a range of flows as compared to the RANS closures. Owing to these differences between the LES and RANS approaches, LES has been shown to be far superior to RANS in accurately predicting turbulent mixing of momentum and scalar (Mahesh et al., 2004), pollutant and heat transport, combustion (Pierce, 2001)), and particle dispersion (Apte et al., 2003b; Ham et al., 2003).

In LES, the Navier-Stokes (NS) equations are filtered in space (as opposed to time as done in RANS) using a local filter (Gaussian, box, spectral etc.) to obtain a filtered velocity field, $\overline{u}_l(\mathbf{x},t)$ (Pope, 2000). Using the local grid resolution as a spatial filter, the small, under-resolved scales of turbulence are filtered out. However, applying the filtering operation to the inertial, nonlinear terms in the NS equations, gives rise to the closure problem. The resulting additional terms need to be modeled. Most often, the models used to close the unknown terms, known as Reynolds stresses, are based on the same types of assumptions, such as the gradient diffusion hypothesis, as employed in RANS. However, the fact that, in LES, modeling is only applied to capture the effect of unresolved, subgrid scales, which are homogeneous and universal, the closure models work very well in a wide range of problems. A dynamic procedure, typically employed in LES subgrid scale modeling, renders the modeling process completely free of any tuning parameters in contrast to RANS. All constants in the model are obtained directly in the calculations and are not set by the user. As long as the grid resolution is sufficient such that the motion of the energy-containing large eddies is captured correctly, unlike RANS, the LES approach can then be used in a truly predictive manner.

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In addition, away from the boundaries, a typical LES grid can be 10 times coarser than a DNS grid in each direction (that is 10 times the Kolmogorov scale), resulting in significant savings in the computational cost. This makes LES an attractive tool compared to the DNS. However, there are still several challenges. Just like DNS, the LES computations are inherently three-dimensional and time-dependent, making the cost of the calculation large as the important large-scale spatio-temporal variations in the flow must still be resolved. In addition, the computational algorithm must not add large amounts of numerical dissipation as it has been shown that dissipative numerical approaches mask the physical dissipation present in turbulent flows and provide inaccurate predictions (Mittal & Moin, 1997; Kravchenko & Moin, 1997). These restrictions typically limits the use of LES to simple, canonical geometries and flows (as free-shear flows (jets, wakes, shear layers), wall bounded channel flows, or flow over backward facing step (Pierce, 2001; Piomelli, 2014)) for which the underlying algorithms are based on a non-dissipative schemes developed for structured Cartesian grids.

Applying LES to the complex and realistic geometries of engineering applications such as the the operating room; including the operating table, surgeons, patient and other equipment, or other applications such as gas-turbine combustors, propellers, among others, requires use of arbitrary shaped unstructured meshes. In recent years; however, considerable progress has been made in handling complex configurations and unstructured grids accurately (Piomelli, 2014). Mahesh et al. (2004); Ham et al. (2003); Mahesh et al. (2006) have developed a numerical algorithm for highfidelity simulations of incompressible, variable density flows on unstructured grids. A novelty of their algorithm is that it is discretely energy-conserving which makes it robust at high Reynolds numbers without numerical dissipation. This makes LES applicable to complex configurations and it has been successfully used to simulate multiphase, spray combustion processes in a realistic Pratt and Whitney gas-turbine combustion chamber (Moin & Apte, 2006; Mahesh et al., 2006; Apte et al., 2009). These simulations are still computationally intensive, often requiring 3-4 weeks of simulation on parallel supercomputers, however, the detailed data obtained from the simulations are of significant importance to researchers and engineers since such information could not be obtained from laboratory experiments. This has led several gas-turbine industries, who generally use RANS in their design cycle, to switch from RANS-based approaches to LES.

Furthermore, turbulent flows laden with dispersed particles (either solid particles, or droplets or

bubbles) involve the complexity of capturing the dynamics of turbulence as well as that of the dispersed phase. The physics of particle-turbulence interactions is complex (Elghobashi, 1994, 2006), and depending upon the magnitudes of the particle relaxation times relative to the Kolmogorov time scales, heavier-than-fluid particles (solid particles, droplets, squames) can exhibit behavior such as preferential clustering on the edges of vortices (Eaton & Fessler, 1994; Rouson & Eaton, 2001; Kulick *et al.*, 2006; Reade & Collins, 2000; Eaton & Segura, 2006), whereas, lighter-than-fluid particles (bubbles) can break the vortical structures (Ferrante & Elghobashi, 2004; Druzhinin & Elghobashi, 1998; Ferrante & Elghobashi, 2007; Sridhar & Katz, 1999).

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RANS is not capable of capturing this complex physics of particles interacting with turbulence because only the mean velocity field is computed by RANS, yet it is commonly used owing to its low cost. However, if the objective is to accurately simulate the dispersion of inertial particles in a turbulent flow, then a three-dimensional, instantaneous velocity field is necessary to calculate the forces on the particles. Inertial particle trajectories and dispersion are strongly influenced by the spatio-temporal variations in the velocity fields. Hence, using only the mean velocity field provides inaccurate dispersion characteristics. An improved RANS to capture the transient effects uses a model for particle motion that utilizes the local turbulence kinetic energy and introduces some randomness (typically a Gaussian distribution) in the particle equations (Sommerfeld et al., 1992) is necessary. Recent work on the dispersion of squames in an operating room and the effect of different inlet air flow conditions used RANS together with such a stochastic, Lagrangian particle-tracking algorithm (Memarzadeh & Manning, 2002). Such a model must be tuned by the user to calculate different particle-laden flows and can behave differently in free-shear versus wall-bounded flows. As can be seen from the results presented by Sommerfeld et al. (1992); Chen & Pereira (1998), particle dispersion predicted using a RANS approach for turbulent flows in a wide range of applications involving swirling, separated flows do not agree with the experimental data. However, the same flowfields computed using LES (Apte et al., 2003b; Moin & Apte, 2006; Apte et al., 2008b, 2009) show considerably better predictive capability and agree with the experimental data very well. In LES, the resolved instantaneous velocity field, which varies in time and space, at the particle location is used to compute the forces on the particles as opposed to the time-averaged velocity in RANS. Accordingly, the effect of the energetic, turbulence scales (of the order of the grid resolution and larger) are completely captured in LES, thus predicting its impact on particle dispersion directly.

To summarize, it is essential to use LES instead of RANS to accurately predict the air circulation and dispersion of squames in an operating room for the following reasons:

- LES provides a three-dimensional, instantaneous flow field (velocity, pressure, temperature) of the resolved, energetic, large-scales, and only models the effect of the unresolved, subgrid (small) scales of turbulence. The subgrid scales tend to be more homogeneous, and less affected by the domain boundary conditions and thus allow the appropriate use of the eddy-viscosity models to calculate their stresses. RANS, on the other hand, only calculates the time-averaged velocity field and models the effect of all the scales of turbulence on the mean flow, resulting in unrealistic flow predictions.
- The subgrid model constants used in LES can be obtained dynamically, thus making LES truly predictive without any user-defined tuning parameters, whereas RANS model constants are not universal and often require manual tuning.
- LES is considerably more accurate in predicting passive as well as inertial particle dispersion since the instantaneous, three-dimensional resolved velocity field is available for computing the forces on the particles. In RANS, a random perturbation must be added to the mean velocity field to construct an artificial, time-dependent, three-dimensional velocity field needed to calculate the particle motion. This renders the calculation of particle dispersion highly inaccurate.

3.2 Governing Equations

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The air flow in an operating room involves temperature variations within the room owing to various sources of heat; such as the operating room lamps, heat radiated from the medical personnel bodies, hot air discharged from a blower system, among others. The local temperature variations change the local air density. However, since the air flow in the room is low-speed (maximum velocity on the order of, $u \sim 0.5$ m/s compared to speed of sound of around, $c \sim 343$ m/s), the Mach number (u/c), that represents the ratio of acoustic to convective time-scales, is small (<< 0.01). Small Mach numbers mean that the convective time-scales are much larger than acoustic time-scales, and thus the compressibility effects are negligibly small. Under these conditions, the variable-density equations in the limit of zero-Mach number are valid and the pressure field at any point within the

domain and time can be split into a bulk thermodynamic pressure, P_0 , and the dynamic pressure p that appears in the momentum equation,

$$P(x,t) = P_0(t) + p(x,t). (1)$$

The background thermodynamic pressure (P_0) for the operating room is assumed constant and equal to the atmospheric pressure, $P_0 = 1$ atm. Accordingly, the density of the air (assumed as ideal gas) varies only with the local temperature field according to the equation of state as,

$$\rho = \frac{P_0 R_{\text{universal}} T}{M_{\text{air}}},\tag{2}$$

where $R_{\rm universal}$ is the universal gas constant, $M_{\rm air}$ is the molecular mass of the air, and T is the absolute temperature. The governing equations for large-eddy simulation of turbulent flows with variable density in the limit of zero Mach number are given below.

364 3.2.1 Gas-phase equations

The spatially filtered, Favre averaged, governing equations used for large-eddy simulation of particleladen, turbulent air flow with heat transfer and buoyancy effects are given as,

$$\frac{\partial \overline{\rho_g}}{\partial t} + \frac{\partial \overline{\rho_g} \tilde{u_j}}{\partial x_j} = 0. \tag{3}$$

$$\frac{\partial \overline{\rho_g} \tilde{u}_i}{\partial t} + \frac{\partial \overline{\rho_g} \tilde{u}_i \tilde{u}_j}{\partial x_j} = -\frac{\partial \overline{p}}{\partial x_i} + \frac{\partial}{\partial x_j} \left(2\overline{\mu} \tilde{S}_{ij} \right) - \frac{\partial q_{ij}^r}{\partial x_j} + (\overline{\rho_g} - \rho_0) g_i, \tag{4}$$

$$\frac{\partial \overline{\rho_g} \tilde{h}}{\partial t} + \frac{\partial \overline{\rho_g} \tilde{h} \tilde{u}_j}{\partial x_j} = \frac{\partial}{\partial x_j} \left(\overline{\rho_g} \tilde{\alpha}_h \frac{\partial \tilde{h}}{\partial x_j} \right) - \frac{\partial q_{hj}^r}{\partial x_j},\tag{5}$$

where

$$\tilde{S}_{ij} = \frac{1}{2} \left(\frac{\partial \tilde{u}_i}{\partial x_j} + \frac{\partial \tilde{u}_j}{\partial x_i} \right) - \frac{1}{3} \delta_{ij} \frac{\partial \tilde{u}_k}{\partial x_k}. \tag{6}$$

Here, $\overline{\rho_g}$ is the filtered density, $\tilde{u_i}$ is the Favre averaged velocity field, \overline{p} is the filtered pressure, μ is the dynamic viscosity, $\alpha_h = k/\overline{\rho_g}C_p$, is the thermal diffusivity (k is the conductivity and C_p the specific heat at constant pressure), g_i is the gravitational acceleration, and $\tilde{S_{ij}}$ is the filtered rate of

strain. In addition, the specific enthalpy, h, is given as,

$$h = \frac{T - T_0}{T_0},\tag{7}$$

where T is the local temperature. Also, T_0 and ρ_0 are the temperature and density fields corresponding to the air inlet conditions and pressure of P_0 .

The additional terms q_{ij}^r and q_{hj}^r in the momentum and the enthalpy equations, respectively, represent the subgrid-scale stress and energy flux and are modeled using the dynamic Smagorinsky model by Moin *et al.* (1991) as demonstrated by Pierce & Moin (1998a). The unclosed terms in Eqs. (4-5) are modeled using the gradient-diffusion hypothesis with eddy-viscosity/diffusivity,

$$q_{ij}^r = \overline{\rho_g}(\tilde{u}_i\tilde{u}_j - \widetilde{u_iu_j}) = 2\mu_t\tilde{S}_{ij} - \frac{1}{3}\overline{\rho_g}q^2\delta_{ij},$$
 (8)

$$q_{hj}^{r} = \overline{\rho_g}(\tilde{h}\tilde{u}_j - \widetilde{hu_j}) = \overline{\rho_g}\alpha_l \frac{\partial \tilde{h}}{\partial x_j}, \tag{9}$$

where the eddy viscosity (μ_t) and eddy thermal diffusivity α_t are modeled as,

$$\mu_t = C_{\mu} \overline{\rho_g} \overline{\Delta}^2 \sqrt{\widetilde{S_{ij}}} \widetilde{S_{ij}}, \tag{10}$$

$$\overline{\rho_g}\alpha_t = C_{\alpha}\overline{\rho_g}\overline{\Delta}^2 \sqrt{\widetilde{S_{ij}}\widetilde{S_{ij}}}.$$
(11)

The coefficients C_{μ} , C_{α} are calculated dynamically at each time-step and for each grid point using the dynamic procedure as outlined by Germano *et al.* (1991). For the unstructured grids, the filter width $\overline{\Delta}$ is taken as $V_{cv}^{1/3}$ where V_{cv} is the volume of the grid element.

3.2.2 Equations for calculating the trajectories of individual squames

The human skin cells or squames typically are disc-shaped with a diameter ranging from 4–20 μ m and a thickness of 3–5 μ m with density close to that of liquid water (1000kg/m³) (Noble *et al.*, 1963; Noble, 1975; Snyder, 2009). Although the squames shape is more disc-like, in the present work they are considered as non-deformable, spherical in shape. A spherical shape is assumed as the dynamics of the spherical particle is easier to calculate and also the lift and drag forces on small particles of disc or spherical shape are not significantly different. The diameter of the spherical

particle is assumed to be 10 microns and matches an average settling velocity of a disc-shaped particle considering the mean flow normal and parallel to the disc (see Appendix A). Recent work using RANS model by Memarzadeh & Manning (2002); Memarzadeh (2003) also approximates the squames particles as spherical with a size of 10 microns.

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An Eulerian-Lagrangian approach is used wherein individual squames trajectories will be tracked in a Lagrangian frame. The different forces on the particles will be calculated using standard closure laws. The effect of the particles on the fluid flow will be negligible owing to their small concentration and thus a one-way coupling approach is adopted, wherein the squame motion uses the fluid flow parameters (velocity) to compute the forces, however, the effect of squames on the fluid momentum is neglected (Elghobashi, 1994, 2006). In addition, since the volume fraction of the squames in an operating room is not very large ($<<10^{-3}$), collisions amongst the squames are neglected. The squame particle motion equation is that of Maxey & Riley (1983),

$$\frac{d}{dt}(\mathbf{x}_p) = \mathbf{u}_p \tag{12}$$

$$\frac{d}{dt}(\mathbf{x}_p) = \mathbf{u}_p
m_p \frac{d}{dt}(\mathbf{u}_p) = \mathbf{F}_g + \mathbf{F}_d + \mathbf{F}_\ell + \mathbf{F}_{am} + \mathbf{F}_p + \mathbf{F}_H,$$
(12)

where \mathbf{x}_p is the particle (squames) centroid location, m_p is the mass of an individual particle, \mathbf{u}_p is the particle velocity, \mathbf{F}_g is the gravitational force, \mathbf{F}_d is the drag force, \mathbf{F}_ℓ is the lift force, \mathbf{F}_{am} is the added mass force, \mathbf{F}_p is the pressure force, and \mathbf{F}_H is the Basset history force. 385

The large ratio of particle density to air density, ρ_p/ρ_g , renders both the Basset history force and the added mass force negligible compared to the drag force. The ratio of the Saffman lift to the drag force is given by, $F_\ell/F_{drag} \sim \rho_g d_p^2 (du/dy)^{1/2}/\mu$, and is dependent on the shear rate and particle diameter. For particles with small diameter and low inertia this force can also be neglected in comparison to the drag force (Crowe et al., 1996; Saffman, 1965). However, the lift force is incorporated in our calculations to account for the saltation of the squame particles from the operating room floor. The gravity, drag and lift forces are given as,

$$\mathbf{F}_g = (\rho_p - \overline{\rho}_g) \mathcal{V}_p \mathbf{g}; \quad \mathbf{g} = -9.81 m/s^2$$
 (14)

$$\mathbf{F}_{d} = -\frac{1}{8}C_{d}\overline{\rho}_{g}\pi d_{p}^{2}|\mathbf{u}_{p} - \tilde{\mathbf{u}}_{g,p}|(\mathbf{u}_{p} - \mathbf{u}_{g,b}); C_{d} = \frac{24}{Re_{p}}(1 + 0.15Re_{p}^{0.687}),$$
(15)

$$\mathbf{F}_{\ell} = -C_{\ell} m_{p} \frac{\overline{\rho}_{g}}{\rho_{p}} (\mathbf{u}_{p} - \tilde{\mathbf{u}}_{g,p}) \times (\nabla \times \tilde{\mathbf{u}}_{g})_{p}; \quad C_{\ell} = \frac{1.61 \times 6}{\pi d_{p}} \sqrt{\frac{\mu}{\overline{\rho}_{g}} |(\nabla \times \tilde{\mathbf{u}}_{g})_{p}|}$$
(16)

where the subscript p represents the squame particle, $\tilde{\mathbf{u}}_{g,p}$ represents the fluid velocity interpolated at the particle center location, \mathcal{V}_p is the particle volume, d_p is the particle diameter, $Re_p = \overline{\rho}_g |\mathbf{u}_p - \tilde{\mathbf{u}}_{g,p}| d_p/\mu$ is the particle Reynolds number, C_d is the drag coefficient, C_ℓ is the lift coefficient.

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The gas-phase velocity, $\tilde{\mathbf{u}}_g$, in the particle equations above, is computed at individual particle locations within a control volume using a generalized, tri-linear interpolation scheme for arbitrary shaped elements. Introducing higher order accurate interpolation is straight forward; however, it was found that tri-linear interpolation is sufficient to represent the gas-phase velocity field at particle locations. As mentioned earlier, in LES of particle-laden flows, the particles are presumed to be subgrid, and the particle-size is smaller than the filter-width used. The gas-phase velocity field required in equations (12) and (13) is the total (unfiltered) velocity, however, only the filtered velocity field is computed in equations (4). The direct effect of the unresolved (subgrid) velocity fluctuations on particle trajectories depends on the particle relaxation time-scale, and the subgrid kinetic energy. Pozorski & Apte (2009) performed a systematic study of the direct effect of subgrid scale velocity on particle motion for forced isotropic turbulence. It was shown that, in poorly resolved regions, where the subgrid kinetic energy is more than 30%, the effect on particle motion is more pronounced. A stochastic model reconstructing the subgrid-scale velocity in a statistical sense was developed (Pozorski & Apte, 2009). However, in well resolved regions, where the amount of energy in the subgrid scales is small, this direct effect was negligible. In the present work, the direct effect of subgrid scale velocity on the droplet motion is neglected. However, it should be noted that the particles do feel the subgrid scale stresses through the subgrid model that affects the resolved velocity field. For well-resolved LES of swirling, separated flows with the subgrid scale energy content much smaller than the resolved scales, the direct effect is shown to be small (Apte et al., 2003h, 2009). This is the main advantage of LES as compared to RANS. In RANS, only the time-average mean velocity is available, and all scales of turbulence affecting the instantaneous fluctuations around the mean

must be modeled. Approximating the effect of turbulent fluctuations on the particle dispersion is
thus necessary for RANS, whereas, it is implicitly accounted for in the LES.

Equations (12,13) are integrated using a fourth-order Runge-Kutta time-stepping algorithm. After obtaining the new particle positions, the particles are relocated, particles that cross interprocessor boundaries are duly transferred, boundary conditions on particles crossing boundaries are applied, source terms in the gas-phase equation are computed, and the computation is further advanced. Solving these Lagrangian equations thus requires addressing the following key issues: (i) efficient search and location of particles on an unstructured grid (ii) interpolation of gas-phase properties to the particle location for arbitrarily shaped control volumes (iii) inter-processor particle transfer. The details on efficiently locating the particles on unstructured grids, search algorithms for particles, and interpolation schemes can be found in the work by Apte et al. (2003b, 2009).

In addition, if the squames impact internal boundaries, a simple, perfectly elastic specular reflection is assumed wherein the squames reverse the wall-normal velocity and preserve the wall-tangential velocity. If the squames impact the patient's knee or the inlet (suction port) of the 3MTM Bair HuggerTM blower system, they are assumed to stick to the surface and are no longer advanced in the computations.

3.3 Computational grid

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Use of high quality computational mesh is critical in LES for accurate prediction of the turbulent flow, but also having a stable numerical solution. However, to handle complex configurations, use of hybrid elements involving tetrahedrons, pyramids, hexagons and wedges, etc. is common in a 437 typical computational grid. This helps with the grid generation surrounding complex features such 438 as the operating table, the surgeons, the patient and the drape, for example. The transitions from 439 one type of grid element to another; however, can lead to skewed elements. It is thus critical that 440 the numerical algorithm be robust, stable and accurate at high Reynolds numbers on skewed or bad 441 grid elements. A numerical algorithm developed for arbitrary shaped unstructured grids (Mahesh et al., 2004; Ham et al., 2003; Ham & Jaccarino, 2004; Mahesh et al., 2006) that is based on kinetic energy conservation principles offers the much needed robustness and accuracy on such grids without resorting to explicit artificial dissipation. As discussed below, we use a research solver based on 445

such an algorithm.

For the present study, a computational mesh (figure 8) was generated using the CAD model described earlier to facilitate predictive large eddy simulations. The mesh was generated using both tetrahedral and hexahedral cells. The transition of mesh from tetrahedral cells to hexahedral cells was done using a combination of pyramid and wedge type cells. Care was taken to generate a computational grid that minimizes the grid skewness as much as possible. As shown below, in the regions away from the complex OR configuration involving the surgeons, the tables, the patient and the drape, a mostly hex-dominant mesh is used. As one approaches closer to the operating table, the computational grid is transitioned to a predominantly tetrahedra-based mesh (see figure 8b). The total mesh count for the computational domain is about 66 million.

Figure 9 shows the grid resolution near the air inlet cross-sections. The grid is appropriately refined to capture the shear layer generated by the inlet flow between the grilles. The mesh surrounding the OR table, patient, surgeons, side tables, the blower, and surgical lamps is predominantly tetrahedral. The tetrahedral mesh was carefully refined to capture surface curvature. Extra refinement was performed near surfaces which were in close proximity to other surfaces. This enhanced mesh refinement is to ensures that the effect of surface shapes on the flow and particles going around them will be captured by the simulation (figure 10a,b.)

As is shown in the above figures, a high quality mesh was generated for the present LES investigation. The minimum tetrahedral cell size (defined as cube root of the cell volume) used near all key regions such as drape, patient, operating bed, surgeons, etc. was around 1mm. Smallest grid spacing in proximity regions resolving the gaps between closely placed surfaces is 0.7mm. The coarsest tetrahedral cell size used away from the key regions is 2.5cm. As mentioned earlier in the report a fine mesh was used near the inlet regions to resolve the flow entering the operating room. A uniform hexahedral cell size of 2.5cm was used to resolve the air inlet grille faces with 20 cells along its width and 44 cells along its length. The gaps between the inlet grilles were resolved using a finer mesh with each cell size of 0.63cm. To capture the inlet air flow structures properly, a refined uniform mesh of 0.38cm was used along the flow direction. Finally, a uniform cell size of 2.5cm was used to resolve each outlet grille with 28 cells along its width and 28 cells along its length. Various mesh metrics were checked to ensure that the quality of the generated mesh was good. Figure 11a shows histogram plot of cell skewness in the mesh. The average skewness was

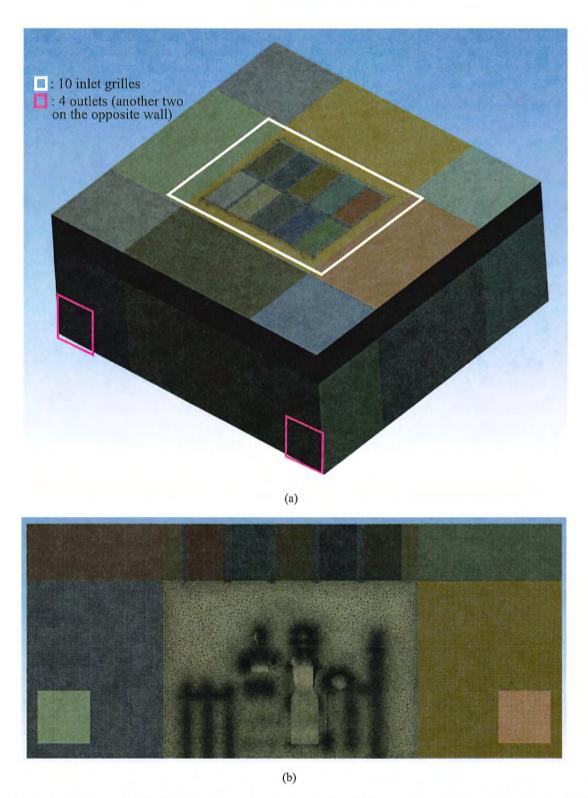


Figure 8: Computational mesh for the operating room model consisting of about 66M hybrid grid elements consisting of hexagons, tetrahedrons, pyramids and wedges: (a) the full 3D mesh, (b) cross-sectional slice showing hex-dominant mesh in the inlet and outlet regions and a tetahedral mesh near the operating table.

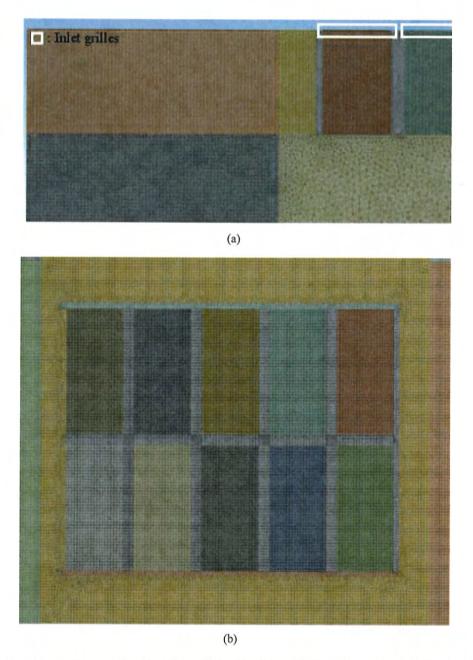


Figure 9: A cross section cut showing fine mesh near the ceiling of the room: (a) top view zoom-in, (b) top view showing all air inlet grilles.

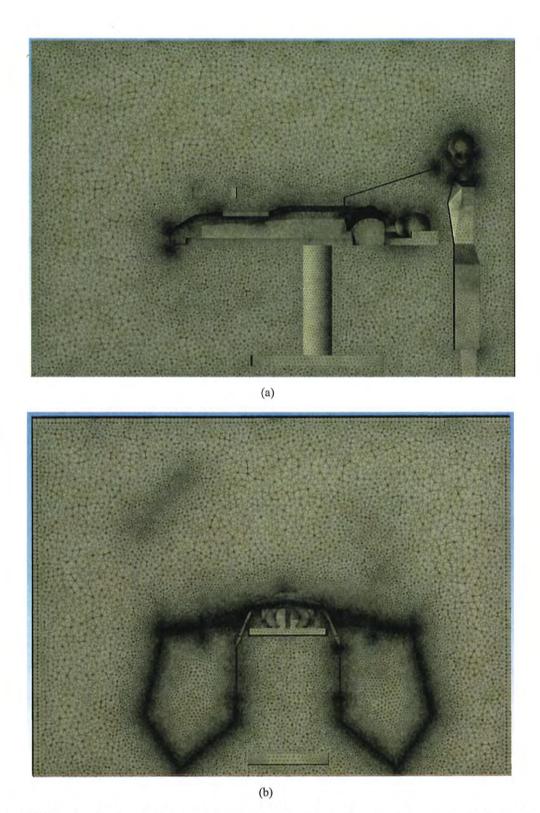


Figure 10: Mesh refinement near curved surfaces and surfaces that are in close proximity to others: (a) side view showing the entire operating table, (b) side view showing drapes.

0.14 and with maximum skewness was 0.91. Only 0.018% of cells had total skewness greater than
0.8 indicating the high quality of cells in the mesh. Another mesh metric that was checked was the
aspect ratio of cells. The maximum aspect ratio was 16.2 and the average cell aspect ratio was 2.9,
which indicate that a majority of cells in the mesh were mostly uniform (see figure 11b).

480 3.4 Boundary Conditions

This subsection provides details of all boundary conditions used in the calculation, starting with operating room (OR) air inlet conditions, heat sources, BH hot air blower inflow (suction) and outflow, and OR air outlet conditions.

3.4.1 Inlet boundary conditions

The dimensions of the operating room are shown in Table 1. As shown, there are 10 inlet grilles supplying air. The net supply air volumetric flow rate, \dot{V} , is 1.10436 m³/s (0.39 ft³/s). Using the inlet flow rates, the air changes per hour (ACH) of the room is calculated as follows,

$$ACH = \dot{V} \times 3600/(LWH) = 24.45 \text{ per hour},$$
 (17)

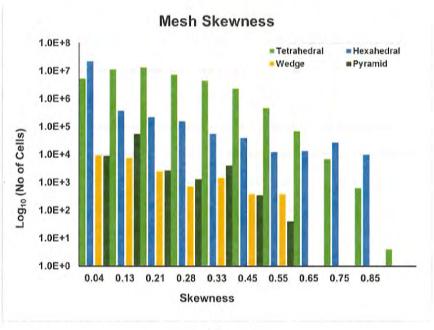
where L, W and H are the room length (in x), width (in y) and height (in z) directions. The ACH is according to the ASHRAE handbook Memarzadeh & Manning (2002), which suggests the ACH to be about 25 per hour for an operating room with recirculating air system.

The inlet boundary conditions are imposed at the 10 grilles on the ceiling of the operating room to model the inlet part of the forced ventilation system. The average inlet velocity, \overline{U}_{in} , is found to be 0.1933m/s based on,

$$\overline{U}_{in} = \dot{V}/(10 \times A_{grill}), \tag{18}$$

where A_{grill} is the area of the cross-section $(1.12 \times 0.51 = 0.5712\text{m}^2)$ and $\dot{V} = 1.1044\text{m}^3/\text{s}$ (39ft³/s) is the net inlet volumetric flow rate. The air temperature of the inlet flow, T_{in} , is set to 59°F (15°C).

Based on Reynolds number for the inlet grilles, $Re_{in} = 9226.54$ (Table 1), the inlet flow is turbulent. In order to have completely predictive numerical simulation and to minimize the effect of boundary conditions, it is necessary to impose a proper, fully developed turbulent flow field at the in-



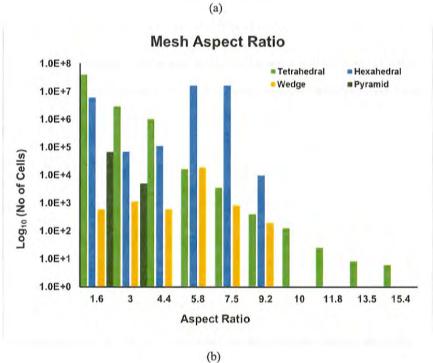


Figure 11: Statistics histograms of the quality of mesh used in the computation: (a) skewness, (b) aspect ratio.

Table 1: Operating room characteristics

Parameter	Value
Room dimensions [m], L, W, H	$7.315 \times 7.00 \times 3.175$
Supply air flow rate [m^3/s], \dot{V}	1.10436
ACH [1/hr]	24.45
Room air temperature [°C]	15
Inler air density [kg/m 3], $ ho_{in}$	1.225
Supply air temperature [°C]	15
Room air pressure [Pa]	1.0131×10^5
Grille dimensions [m]	1.12×0.51
Grille Area [m²]	0.5712
Grille hydraulic diameter [m], D_h	0.7
Mean inlet velocity [m/s], \overline{U}_{in}	0.1933
Inlet Reynolds number, $Re_{in} = \frac{\rho_{in}\overline{U}_{in}D_h}{\mu}$	9226.54

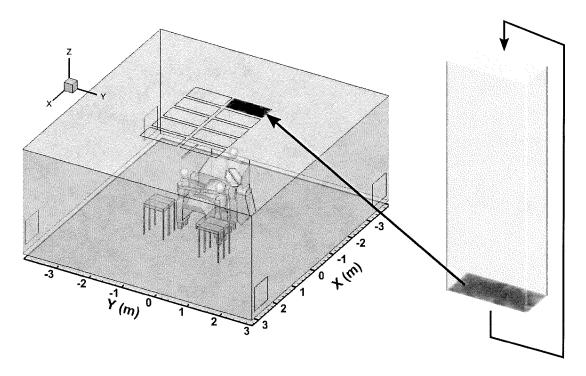


Figure 12: Schematic of the periodic duct used to generate inlet flow data.

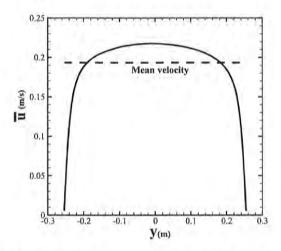


Figure 13: Mean velocity profile generated by a periodic duct flow for the inlet grilles.

let. Thus, a periodic turbulent duct flow was computed (figure 12) to produce a target mean flow rate equal to that prescribed ($\dot{V}=1.10436 {\rm m}^3/{\rm s}$) using a body force technique of Pierce & Moin (1998b). This also generates turbulence fluctuations at the inlet plane that satisfy the continuity equation. The cross-sectional area of the periodic duct used is the same as that of each grille (1.12m × 0.51m), and the length is about 4.5 times the hydraulic diameter of the cross-section. The velocity field data at the inlet cross-section was recorded in time series for almost 400 seconds of physical time. Figure 13 shows the time-averaged velocity field in the center plane of the duct obtained from the periodic duct simulation. The turbulence intensity ($I=\sqrt{\frac{1}{3}(u_{rms}^2+v_{rms}^2+w_{rms}^2)/\overline{U}_{in}}$) at the inlet cross-section is 5-6% of the mean inlet velocity (\overline{U}_{in}), and is in agreement with the experimental measurements conducted by McNeill et al. (2012, 2013). Here, u_{rms} , v_{rms} and w_{rms} are the root-mean square velocity components in the x, y and z directions, respectively.

3.4.2 Hot air blower and other heat sources

A 3MTM Bair HuggerTM 750 blower draws air from the floor of the operating room, heats it and blows it into the blanket (3MTM Bair HuggerTM Model 522) that covers the torso region of the patient. The blanket is covered with a plastic drape. The maximum flow rate of the blower is $\dot{V}_{blower} = 0.021 \text{m}^3/\text{s}$. The hot air moves along the surface of the drape that faces the patient and then it is discharged into the room along the drape edges. In the present calculation, the bottom surface (facing the floor) of the 3MTM Bair HuggerTM blower is considered as a suction surface with

surface area ($A_{extraction} = 0.03796\text{m}^2$). A Dirichlet boundary condition is applied at this surface that prescribes the extraction velocity $\overline{U}_{extraction}$ as

$$\overline{U}_{extraction} = \frac{\dot{V}_{blower}}{A_{extraction}},\tag{19}$$

giving an extraction velocity of 0.5532m/s. To model the hot air discharged along the edges of the drape. The total area of this edge of the drape is measured to be $A_{drape} = 0.07794$ m². A Dirichlet boundary condition is applied such that the air is injected into the room perpendicular to the edges of the drape with velocity, \overline{U}_{drape} , calculated as,

giving an average injection velocity along the drape edge as 0.2694 m/s. The temperature of the

$$\overline{U}_{drape} = \frac{\dot{V}_{blower}}{A_{drape}},\tag{20}$$

hot air at the BH blower outlet is prescribed equal to 109°F (42.77°C) and the temperature of the air 510 leaving the drape edge is set equal to 106°F (41.11°C) according to 3M video at: 511 https://www.youtube.com/watch?v=QhzeInWlJ54. The flow rates at the inlet grilles and for the 512 blower are summarized in Table 3.4.2. 513 Other heat sources in the surgical room are mainly the surgeons, patient, surgical lamps, and 514 exposed surface of the patient's knee. These heat sources can cause warming of the air in contact 515 with the surfaces and result in a rising thermal plume. For these surfaces, a Dirichlet condition was 516 used for temperature based on the experimentally measured values. In their work, McNeill et al. (2012) conducted detailed measurements of detailed surface temperatures that may lead to buoyant 518 plumes specifically to be used in CFD calculations. The values are summarized in Table 3.4.2, 519 among which, the temperatures of surgeons and patient's heads as well as the surgical lamps are 520 based on the work of McNeill et al. (2012) and the rest are from the 3M video. For all other other

3.5 Numerical solution method

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The computational approach is based on a co-located, finite-volume, energy-conserving numerical scheme on unstructured grids (Moin & Apte, 2006; Mahesh et al., 2006) and solves the variable

solid surfaces, a no heat flux Neumann condition was specified, $\frac{\partial T}{\partial n} = 0$.

Table 2: Flow and temperature conditions

Parameter	Value
Inlet volume flow rate \dot{V} , [m ³ /s]	1.1044
Temperature of inlet grille air, [°C]	15
Mean inlet velocity $[m/s]$, \overline{U}_{in}	0.1933
BH blower volume flow rate \dot{V}_{blower} , [m ³ /s]	0.021
Temperature of hot air leaving the drape edge, [°C]	41.11
Heads of the surgeons and patient, [°C]	31.44
The patient's knee, [°C]	37.78
Two surgical lamps, [°C]	93.92

density gas-phase flow equations in the limit of zero-Mach number. In this co-located scheme, the velocity and pressure fields are stored and solved at the centroids of the control volumes. Numerical solution of the governing equations of the continuum fluid phase and particle phase (squames) are staggered in time to maintain time-centered, second-order advection of the fluid equations. Denoting the time level by a superscript index, the velocities are located at time level t^n and t^{n+1} , and pressure, density, viscosity, and the scalar fields at time levels $t^{n+3/2}$ and $t^{n+1/2}$. Squames position and velocity are advanced explicitly from $t^{n+1/2}$ to $t^{n+3/2}$ using fluid quantities at time-centered position of t^{n+1} .

3.5.1 Advancing the Lagrangian squames equations

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The squames (particles) equations are advanced using a fourth-order Runge-Kutta scheme. Owing to the disparities in the flow field time-scale (τ_f) and the squames relaxation time (τ_p) sub-cycling of the squames equations may become necessary. Accordingly, the time-step for squames equation advancement (Δt_p) is chosen as the minimum of τ_p and the time-step for the flow solver (Δt). For the present simulations, the squames relaxation time, τ_p , based on the drag force, was found to be always larger than the time-step, Δt , used for solving the fluid flow equations in LES. Thus, the temporal evolution of the squames was well resolved by the flow time step, and subcycling of the particle equations was not necessary.

After obtaining their new positions, the squames are relocated, and the squames that cross interprocessor boundaries are duly transferred. Boundary conditions for squames crossing boundaries are applied and the computation is further advanced. Solving these Lagrangian equations thus requires addressing the following key issues: (i) efficient search for locations of squames on an unstructured grid, (ii) interpolation of gas-phase properties to the squames location for arbitrarily shaped control volumes, (iii) inter-processor transfer of the squames.

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Locating the squames particles in a generalized-coordinate structured code is straightforward 549 since the physical coordinates can be transformed into a uniform computational space. This is not the case for unstructured grids used in the present simulations (Apte et al., 2003b,a, 2009). The ap-551 proach used here, projects the squames location onto the faces of the control volume and compares 552 these vectors with outward face-normals for all faces. If the particle lies within the cell, the pro-553 jected vectors point the same way as the outward face-normals. This technique is found to be very accurate even for highly skewed elements. A search algorithm is then required to efficiently select 555 the control volume to which the criterion should be applied. An efficient technique termed as 'the 556 known vicinity algorithm' was used to identify the control volume number in which the particle lies. 557 Given the previous particle location, the known-vicinity algorithm identifies neighboring grid cells by traversing the direction the particle has moved. In LES, the time steps used are typically small 559 in order to resolve the temporal scales of the fluid motion. Knowing the initial and final location of 560 the particle, this algorithm searches in the direction of the particle motion until it is relocated. The neighbor-to-neighbor search is extremely efficient if the particle is located within 5-10 attempts, 562 which is usually the case for 98% of the squames in the present simulation. Once this cell is iden-563 tified, the fluid parameters are interpolated to the particle location using a generalized, tri-linear 564 interpolation scheme for arbitrary shaped elements. Introducing higher order accurate interpolation is straight forward; however, it was found that tri-linear interpolation is sufficient to represent the 566 gas-phase velocity field at particle locations. In the present case, particles are distributed over sev-567 eral processors used in the computation, and the load-imbalance was not significant. Details of the 568 algorithm can be found in Apte et al. (2003b, 2009). The overall increase in computational cost due 569 to addition of about 3 million particles was about 25% per time-step.

3.5.2 Advancing the Eulerian fluid flow equations

The scalar field (enthalpy or non-dimensional temperature; equation 5) is advanced using the old time-level velocity field. A second-order WENO scheme is used for scalar advective terms and centered differencing for the diffusive terms. All terms, except the source terms due to buoyancy effect, are treated implicitly using Crank-Nicholson for temporal discretization. Once the scalar field is computed, the density and temperature fields are obtained from constitutive relations (equation 7) and the ideal gas law (equation 2). The cell-centered velocities are advanced in a predictor step such that the kinetic energy is conserved. The predicted velocities are interpolated to the faces and then projected. Projection yields the pressure at the cell-centers, and its gradient is used to correct the cell and face-normal velocities. The steps involved in solving the projection-correction approach for velocity field are briefly described below, Details of this algorithm may be found in Moin & Apte (2006); Mahesh et al. (2006); Apte et al. (2008b).

• Advance the fluid momentum equations using the fractional step algorithm. The density field is available at intermediate time level is obtained from arithmetic average at the two time steps $t^{n+3/2}$ and $t^{n+1/2}$.

$$\frac{\rho u_i^* - \rho u_i^n}{\Delta t} + \frac{1}{2V_{cv}} \sum_{\text{faces of cv}} \left[u_{i,f}^n + u_{i,f}^* \right] g_N^{n+1/2} A_f = \tag{21}$$

$$\frac{1}{2V_{cv}} \sum_{\text{faces of cv}} \mu_f \left(\frac{\partial u_{i,f}^*}{\partial x_j} + \frac{\partial u_{i,f}^n}{\partial x_j} \right) A_f + (\rho - \rho_0) g_i$$

where f represents the face values, N the face-normal component, $g_N = \rho u_N$, and A_f is the face area. The superscript '*' represents the predicted velocity field, and $g_N^{n+1/2} = 0.5(g_N^n + g_N^{n+1})$.

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 Interpolate the velocity fields to the faces of the control volumes and solve the Poisson equation for pressure:

$$\nabla^{2}(p\Delta t) = \frac{1}{V_{cv}} \sum_{\text{faces of cv}} \rho_{f} u_{i,f}^{*} A_{f} + \frac{\rho^{n+3/2} - \rho^{n+1/2}}{\Delta t}$$
 (22)

Reconstruct the pressure gradient, compute new face-based velocities, and update the cv-velocities using the least-squares interpolation used by Mahesh et al. (2004); Ham et al. (2003); Mahesh et al. (2006),

$$\frac{\rho\left(u_i^{n+1} - u_i^*\right)}{\Delta t} = -\frac{\delta p}{\delta x_i}.$$
 (23)

4 Results

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The numerical simulation was initiated with stagnant air (zero velocity) in the operating room and 587 proper boundary conditions. A simulation was carried out with the blower off and all surfaces at 588 room temperature for about 67s of physical time, which corresponds to about 4 flow through times 589 based on the average inlet air velocity and the height of the room. After the initial transients, the 590 thermal boundary conditions were applied at the surgeons heads, the patient's knee, the surgical 591 lights. A calculation was performed for another 54s to establish a stationary flow with the thermal 592 plumes created by the surfaces with higher-than-ambient temperatures. At this time, calculation 593 of statistics for time-averaged mean velocity field and turbulence intensity were initiated and also 3 594 million squame particles were placed at the floor in three different regions surrounding the operating table as described below. With the blower-off the time-step used in the calculation was $\Delta t = 6 \times$ 10^{-5} s giving a CFL number of about 0.75. This time step was able to resolve the important time-597 scales of turbulence and particle motion accurately. The flow statistics were collected for a total 598 of 80s after a stationary flow field was established and the squames trajectories were calculated for 599 about 21s.

After the above calculation was completed, the remaining squames particles in the computational domain were removed, and the blower was turned on. With the blower discharging a hot air at higher speeds, the time-step was reduced by a factor of 2.5 to $\Delta t = 2.4 \times 10^{-5}$ s maintaining the CFL number about 0.6. The reduction in time step is related to both the explicit treatment of the gravitational source term in the momentum equation as well as increased velocity at the blower discharge location. A calculation was performed for about 30s to obtain a developed plume from the hot air discharged by the blower. Flow statistics and the initial location of 3 million squames particles were initiated. With the blower-on, the flow statistics were collected for about 37s and particle trajectories were calculated for about 30s.

All calculations were performed on a parallel computer and used 1600 processors. The computational domain was decomposed such that each processor contains roughly the same number of control volumes. The overall calculation (including initial transient, the case with blower-off and the case with blower-on including particle trajectories for both cases) took about 2M CPU-hrs. For the case of blower-off, about 20s of physical time would cost roughly 100,000 CPU-hours, whereas

the same calculation with blower-on would cost roughly 220,000 CPU-hours. For each case, tracking 3 million trajectories of squames would add about 20-30% additional computing cost. This is
because, initially the 3 million squames are clustered in a small region near the floor causing load
imbalance as the particles were present on only a few processor domains. The flow statistics and
particle trajectories are discussed below.

620 4.1 Flow characteristics

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Figures 14a and 14b show the locations of two slices through the three-dimensional computational domain at x = -0.88m and y = -0.162m for which the mean velocity magnitude, turbulence intensity, and instantaneous temperature contours are plotted. The x = -0.88m slice shows a planar cut that includes the surgical lamp and the operating table (OT). The y = -0.162m slice shows a side view and contains 2 medical staff, a side table, the surgical lamp, and part of the inverted U-shaped drape. For these two slices, the flow characteristics with blower-off and blower-on are compared.

Figures 15, 16, and 17 show the contours of mean velocity magnitude, turbulence intensity, and instantaneous temperature, respectively, for the two cases of blower-off and blower-on. For the case of blower-off, figure 15a shows that the ventilation air from the ceiling inlet grilles moves downwards, gets deflected by the surgical lights and the table, impinges on the floor farther away from the table, and finally exits through the outlet grilles. Large recirculation regions are created on both sides of the table. The flow is not symmetric owing to asymmetries in the configuration itself. In comparison, with the blower turned on, the flow underneath and around the table is considerably modified as can be seen from the large velocity magnitudes under the table (figure 15b). The recirculation region is also disrupted by the rising air from the hot blower discharge. This difference is clearly visible from the turbulence intensity contours shown in figure 16a,b. With the blower-off, the maximum turbulence intensity level is about 30% in the high shear regions between the inlet air streams, as well as near the warm surgical lights due to the buoyant plume. With the blower-on, the turbulence intensity level is as high as 60% in regions affected by the rising thermal plumes from the blower hot air. The instantaneous temperature contours shown in figure 17a,b confirm that the increased turbulence level is mainly because of the thermal plumes from the hot blower air as can be seen by the high temperature regions under the OT.

Figures 18, 19, and 20 show the contours of mean velocity magnitude, turbulence intensity, and

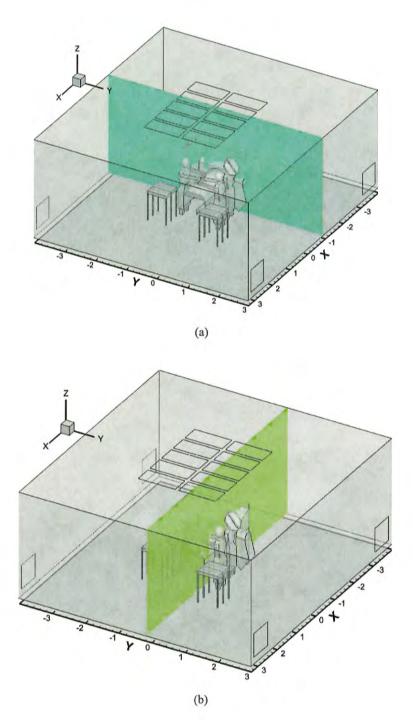


Figure 14: Locations of the planes for which contour plots of mean velocity magnitude, turbulence intensity and instantaneous temperature are presented to compare the effect of the blower discharge on the flowfield: (a) x = -0.88m (b) y = -0.162m.

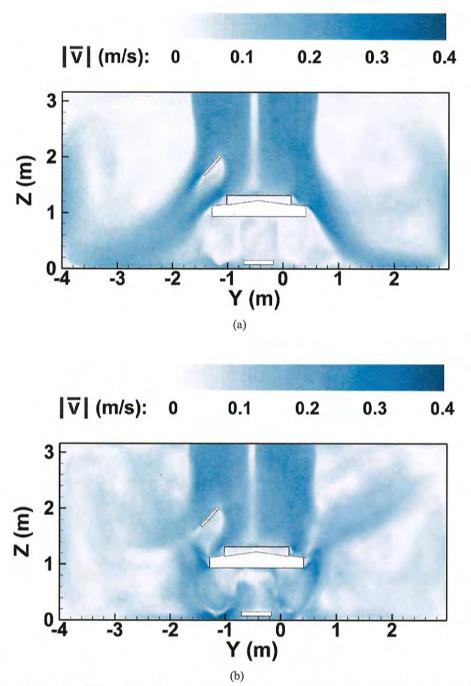


Figure 15: Contours of the mean velocity magnitude at x = -0.88m (a) with blower-off and (b) with blower-on. The time average is taken over a physical time of 80s (no blower) and 37s (with blower) after establishing a stationary state.

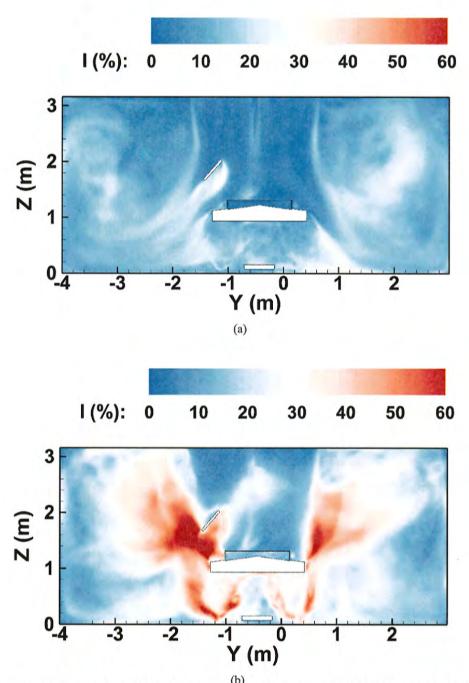


Figure 16: The turbulence intensity contours at x = -0.88m (a) with blower-off and (b) with blower-on. The time average is taken over a physical time of 80s (no blower) and 37s (with blower) after establishing a stationary state.

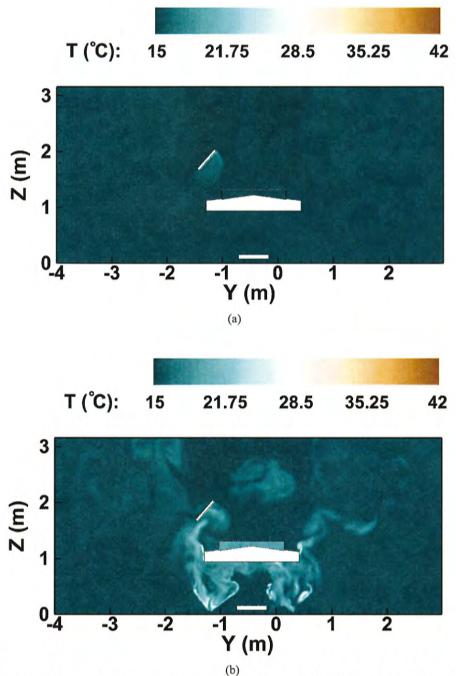


Figure 17: The instantaneous temperature contours at x = -0.88m (a) with blower-off and (b) with blower-on. These snapshots are at about 35s after a stationary flow field was obtained and calculation for flow statistics was initiated.

instantaneous temperature, respectively, for the cases of blower-off and blower-on at y = -0.162m. 644 Similar trends as described before are observed. The hot blower air and the rising thermal plumes 645 disrupt the downward ventilation air flow. The high temperatures and turbulence intensity under the 646 inverted U-shaped drape are clearly visible. The flow is also highly asymmetric with the blower 647 turned on owing to the orientation and location of the drape. It is also seen from figure 20b that 648 the rising thermal plumes may reach the ceiling in some regions. With the blower off, however, the plumes from warm surfaces of surgical lights, surgeons heads, and patient's knee are weak and are 650 not significant enough to disrupt the downward ventilation air flow. 651

Dispersion of squames 652

This section provides details of the initial locations of the squames, their trajectories, and statistics of sampling the particles in regions of interest with high potential of reaching the surgical site.

4.2.1 Initial locations of squames 655

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In order to provide a worst-case (or least probable) scenario for the squames to be carried to the 656 surgical site by the air convection, all 3 million squames were initially placed on the floor and randomly distributed in a small region surrounding the operating table within a height of about 1 cm above the floor of the OR. If these squames are lifted by the turbulent air and moved to the surgical 559 site, other effects such as motion of medical equipment and staff, additional squames shed from the 560 heads and faces of medical staff, surgical garments, etc. will have an even higher probability to reach the surgical site.

Table 3: Coordinates of color-coded regions for initial positions of squames as shown in figure 21.

Color-coded initial position	$(x,y,z)_{min}$ [m]	$(x, y, z)_{max}$ [m]
Red	(-1.40, -0.025, 0.0)	(0.70, 0.40, 0.01)
Green	(-1.40, -0.025, 0.0) (-1.80, -1.35, 0.0)	(-1.4, 0.4, 0.01)
Yellow	(-1.40, -1.35, 0.0)	(0.70, -0.855, 0.01)

Three million particles with a diameter of 10 micron are placed within a 1 cm thick layer above the floor of the OR. The region where the particles are located is around the OT, surrounding the feet of four surgeons present in the CAD model. To better visualize the trajectories the squames

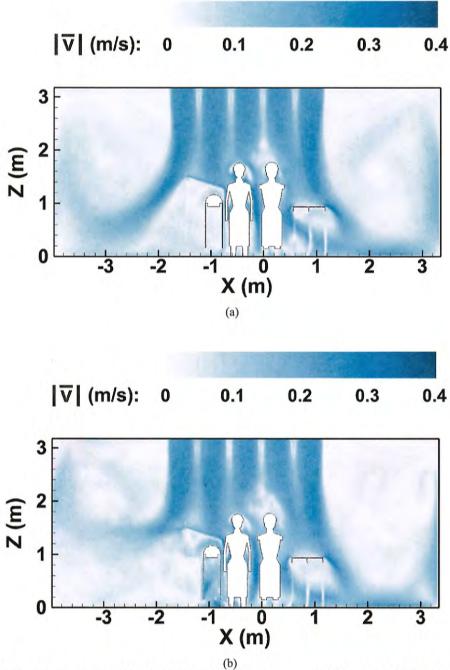


Figure 18: Contours of the mean velocity magnitude at y = -0.162m (a) with blower-off and (b) with blower-on. The time average is taken over a physical time of 80s (no blower) and 37s (with blower) after establishing a stationary state.

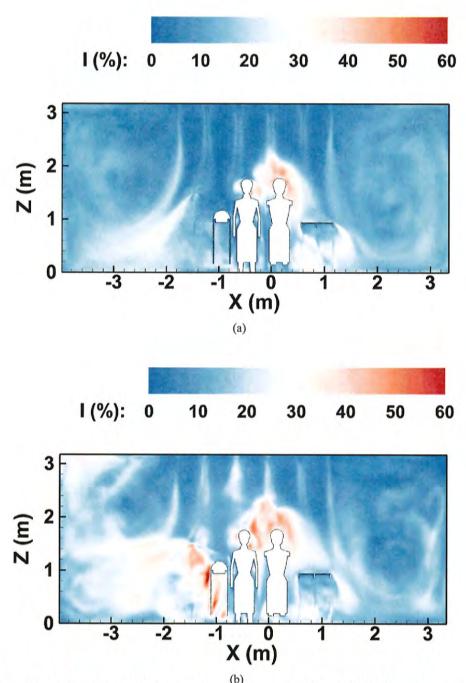


Figure 19: The turbulence intensity contours at y = -0.162m (a) with blower-off and (b) with blower-on. The time average is taken over a physical time of 80s (no blower) and 37s (with blower) after establishing a stationary state.

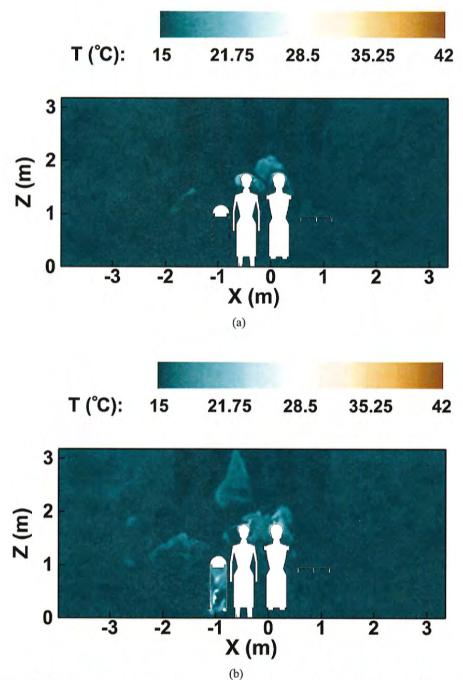


Figure 20: The instantaneous temperature contours at y = -0.162m (a) with blower-off and (b) with blower-on. These snapshots are at about 35s after a stationary flow field was obtained and calculation for flow statistics was initiated.

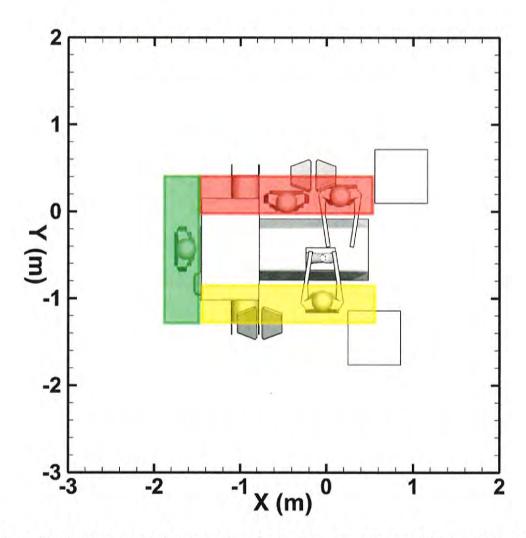


Figure 21: Three color-coded regions where the 3 million squames were initially distributed within a 1 cm height from the floor.

from different initial locations, the U-shaped region is divided into three rectangular sections color-coded as (i) red, (ii) green and (iii) yellow as shown in figure 21. One million squames are placed in each of the three sections at the same time, providing equal probability for the statistical analysis of motion of squames. The position of an individual squame particle in a section is chosen randomly using a uniform distribution. The squames of each section are tagged with distinct IDs. The actual coordinates of the three sections are given in Table 3.

4.2.2 Trajectories and snapshots of squames

In order to visualize the effect of the hot blower air on the trajectory of squames, instantaneous scatter plots of squames are displayed at 10s and 20s after their initiation with blower-off and blower-on in figures 22a,b and 23a,b, respectively. The squames are also color-coded based on their region of origin as highlighted in figure 21. Drastic differences between the blower-off and blower-on cases are observed. It is clear from figures 23a that the majority of the squames are dispersed by the ventilation air flow towards the outlet grilles when the blower is off. None of the squames actually rise to the level of the side tables or the OT. In contrast, in the case of blower-on, a large number of squames are lifted upwards by the rising thermal plumes. Some of the squames (mostly red-colored and some yellow-colored) are lifted above the surgeons heads and are blown towards the OT by the incoming ventilation air. Large number of squames are seen to be above the OT, several are surrounding the surgeons hands, above the side tables, and some are very close to the patient's knee and the surgical site. This is better visualized by the zoom-in view shown in figures 24a,b.

Figures 25, 26, and 27 show a different view angle for the squames at the same time instances as in the above discussion. It is again seen that with the blower-on several particles are lifted upwards by the thermal plumes and rise above the operating table and then are blown downwards by the incoming ventilation air.

Finally, figure 28 shows an instantaneous snapshot of squames very close to the patient's knee. It seen that several of the red-coded particles are near the bottom of the knee, whereas some yellow-coded particles are in the very close vicinity of the surgical site. Several particles are still suspended above the OT and are being transported downwards by the ventilation air and may potentially reach close to the surgical site.

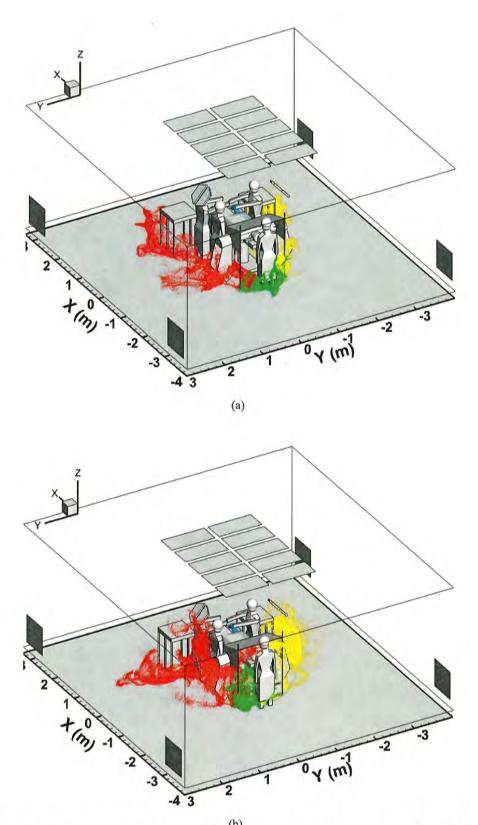


Figure 22: Instantaneous scatter plot of squames color-coded by their region of origin at 10s after initiation: (a) blower-off, (b) blower-on.

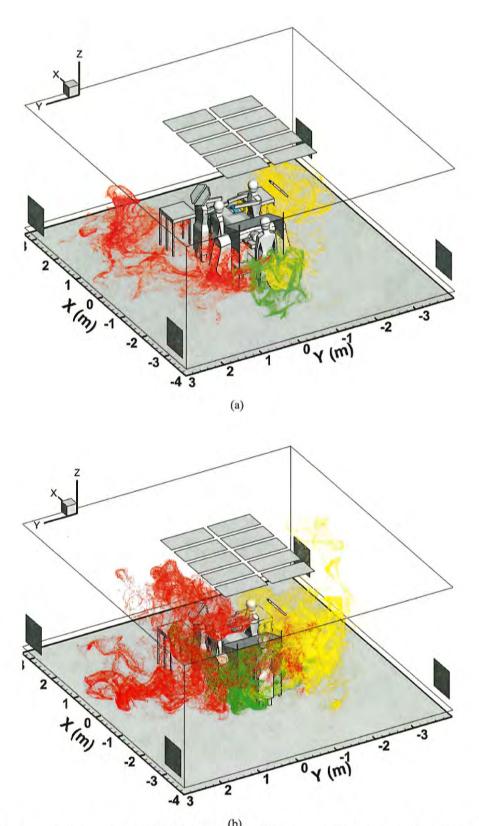
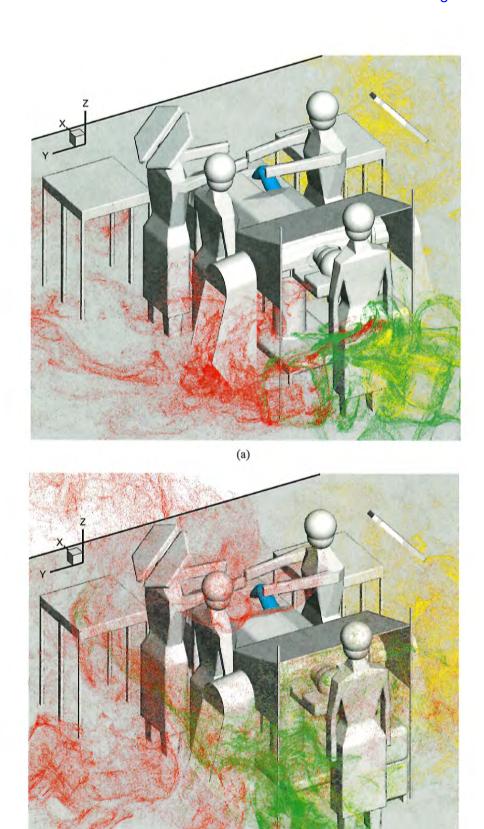


Figure 23: Instantaneous scatter plot of squames color-coded by their region of origin at 20s after initiation: (a) blower-off, (b) blower-on.



(b) Figure 24: Zoom-in of the instantaneous scatter plot of squames color-coded by their region of origin at 20s after initiation: (a) blower-off, (b) blower-on.

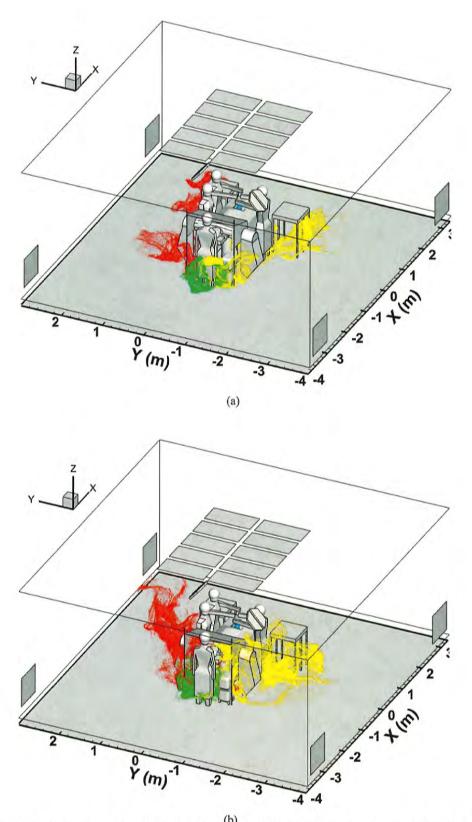


Figure 25: Instantaneous scatter plot of squames color-coded by their region of origin at 10s after initiation: (a) blower-off, (b) blower-on.

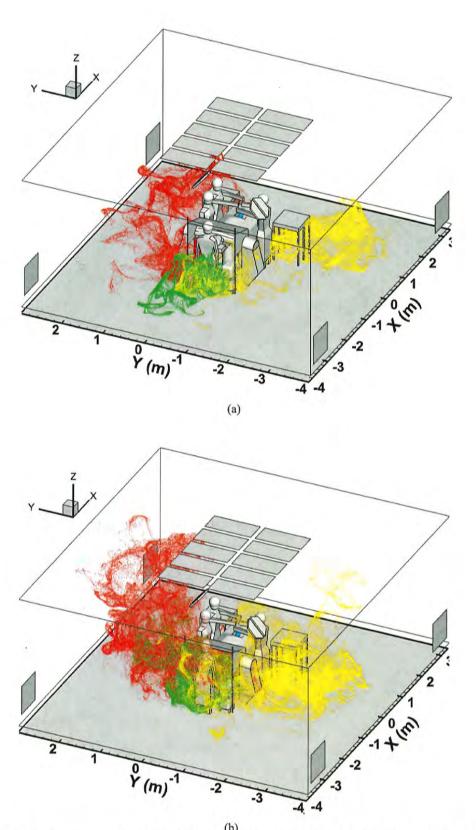
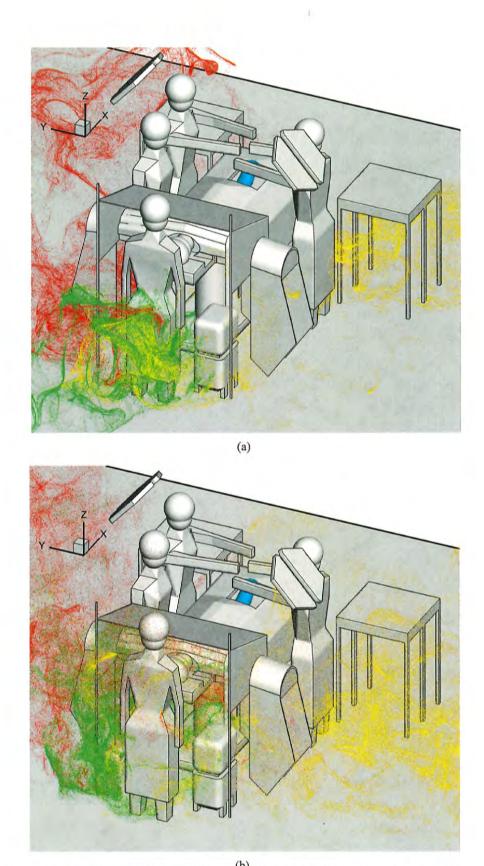


Figure 26: Instantaneous scatter plot of squames color-coded by their region of origin at 20s after initiation: (a) blower-off, (b) blower-on.



(b) Figure 27: Zoom-in of the instantaneous scatter plot of squames color-coded by their region of origin at 20s after initiation: (a) blower-off, (b) blower-on.

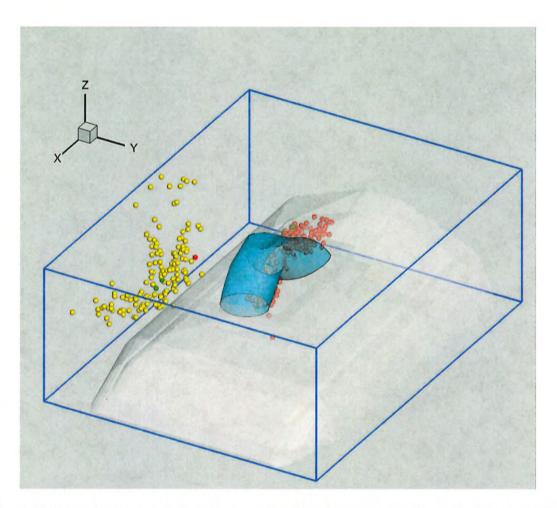


Figure 28: Zoom-in showing the instantaneous snapshot of squames near the surgical site at t = 27s.

694 4.2.3 Number density of squames in the regions of interest

To assess the probability of squames reaching the surgical site, four imaginary boxes were located as follows: two boxes covering the two side tables, a box around the OT, and a box around the patient's knee area. The surgeons and medical assistants are bound to use surgical instruments placed on the side tables. The possibility of squames reaching the surgical site is then dependent on the number density of squames within these four imaginary boxes (see figure 29). The number of squame particles inside the four boxes are recorded in time. A blue box (figure 29 (a) and (c)) is covering the whole OT. The top of this box is about 30 cm high, including the patient's whole body and the surgeons hands. An orange box (figure 29 (b) and (d)) is placed above the OT, just covering the patient's knee and part of the surgeon's hands; and the top of the box is only 2 cm above the surgeon's hands. One purple box (figure 29 (a) - (d)) is placed on each of the two side tables. The height of these boxes is about 1 cm, so that any surgical instrument placed on the side tables would be within the box.

Two computations of the trajectories of squames were performed after a statistically stationary flow field has been reached for the cases of blower-off and blower-on. Based on the average inlet air velocity and the height of the room, it takes 15-20s for a fluid particle to travel from the ceiling grille to the floor. First, the blower is turned off and only the ventilation air from the inlet grilles and thermal plumes created by the warm surfaces including surgical lights, surgeons' heads, patient's head, and patient's knee are responsible for the dispersion of squames. It was found that all the squames initiated in all three sections (red, green and yellow) are basically transported by the air flow reaching the floor and quickly dispersed to the for outlet grilles. After a calculation of about 25s of physical time, some squame particles do rise to the underside of the side tables, but none of the squames was found to enter the four imaginary boxes representing the regions of interest. It was concluded that without the hot air discharged from the blower, the ventilation air circulation alone cannot disperse the squames to the surgical site. The thermal plumes from various warm surfaces only slightly affect the air coming from the inlet grilles and do not affect the motion of the squames.

a flow field with well established thermal plumes created by the hot air discharged from the blower. After reaching a stationary state, the squames were initiated in the same color-coded sections and the

With the blower turned on, computations were carried out for about 30s of physical time to obtain

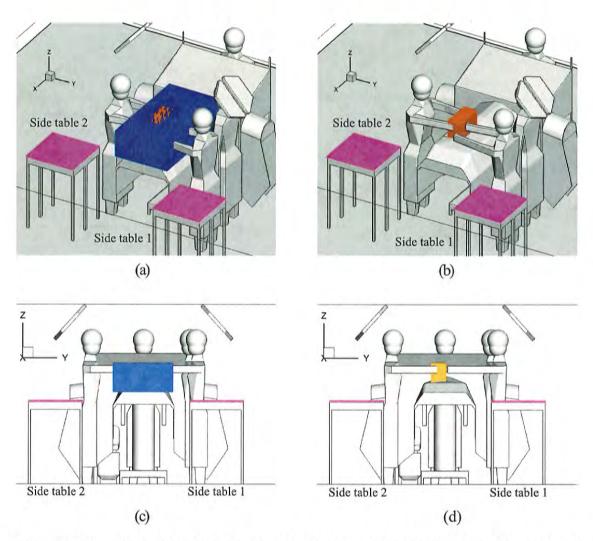


Figure 29: Four color-coded regions of interest, for recording the temporal history of the number of squames reaching them, shown in different views (a–d). The regions of interest include the zones above the two side tables, above the OT, and above the patient's knee.

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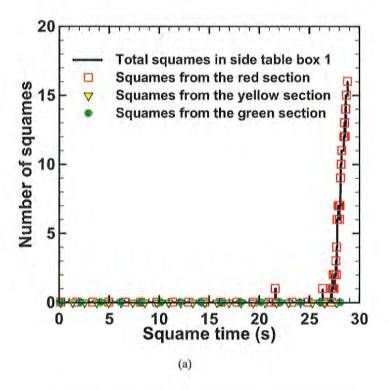
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computation continued for another 30s. With the blower on, hot air is discharged through the sides covering the patient's arms into the ambient air and strong thermal plumes rise under the operating table. Some of the edges of the drape are very close to the floor (see figure 4b) and the hot air plume drags squames with it making them rise upwards faster than in the case when the blower was off. A majority of the squame particles are transported away from the table towards the outlet grilles. However, a statistically significant number of particles are lifted above the operating table with some even reaching the height of the surgeons. The particles rise due to buoyancy and then get flushed down onto the operating table by the incoming ventilation air from the inlet grilles. The particles then do enter the imaginary boxes of interest, specifically above the operating table and the patient's knee.

Figures 30 and 31 show the number of squame particles as a function of time entering the four imaginary boxes of interest (above the side tables, above the operating table, and patient's knee). It can be seen from Figure 31b that no particles are found inside these boxes for the first 17s, which is about the time needed for the ventilation air to travel from the ceiling to the floor. After this time, the number of squame particles in the box above the OT increases almost in a linear fashion. Within 30s of physical time, the number of squame particles within the OT box are about 2500 and increasing. Figure 31a shows that at about 23s, some of the particles above the OT start to enter the box above the knee, which is a very narrow zone surrounding the patient's knee. The number of these particles increases linearly to about 600. Note that some of these particles do get trapped at the knee, some are carried away by the air flow and hence the number appears to be decreasing after about 25s. From the instantaneous snapshot of the squames shown in figures 24b and 27b, it can be seen that several particles are still above the OT and moving downward due to the air from the inlet grilles. It is thus expected that more particles will enter the box above the patient's knee, potentially raising the probability of infection. It is also interesting to note that the squame particles entering the box above the OT and above the knee are mainly the red-colored particles initiated from the side of the table with two surgeons. Owing to the asymmetry in the CAD model geometry, the flow pattern around each side of the table is different and the recirculation region created by the incoming air from the inlet grilles is also asymmetric. The rise and eventual trapping of the squames within the knee box is thus also related to which side of the table it originated from. The boxes above the side tables also entrain about 15 squame particles as can be seen from figures 30a,b. This suggests that



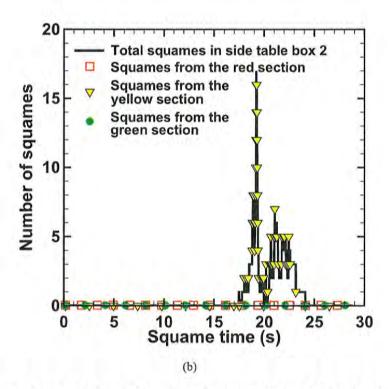
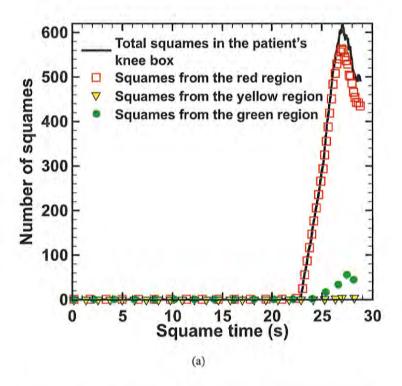


Figure 30: Temporal history of the total number of squames (shown by black color) entering four different regions of interest: (a) side table box 1, and (b) side table box 2Also shown in color is the number of color-coded squame particles entering from the red, green and yellow regions of the figure 21.



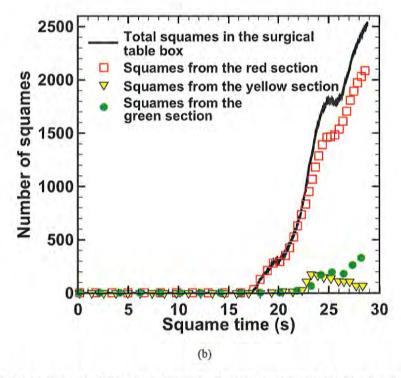


Figure 31: Temporal history of the total number of squames (shown by black color) entering four different regions of interest: (a) the patient's knee area, and (b) the OT box. Also shown in color is the number of color-coded squame particles entering from the red, green and yellow regions of the figure 21.

the surgical instruments on the side tables also have a small probability of carrying squames to the surgical site.

5 Summary and Concluding Remarks

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A high-fidelity, large-eddy simulation (LES) was performed to study the interaction of the operating room (OR) ultra-clean ventilation air flow and the flow created by a forced air warming system 757 (3MTM Bair HuggerTM blower) and its impact on the dispersion of squames particles. A full three-758 dimensional design of an OR with operating table (OT), surgical lamps, medical staff, side tables, 759 a blower, and a patient undergoing knee surgery was constructed. Unstructured grid elements involving hexahedra, tetrahedra, pyramids and wedges were used to capture the complex geometry of 761 the OR. An arbirary shaped, unstructured grid flow solver for LES based on governing equations 762 for variable density in the limit of zero-Mach number was used. Ultraclean ventilation air enters the OR through 10 ceiling grilles with air changes per hour (ACH) of 24.45 and flow Reynolds number, based on the air inlet grille size and mean air inlet velocity, of 9226. The air inlet flow was 765 developed from a periodic duct flow with the required target mass flow rate for each grille. No-slip 766 conditions were applied for all solid surfaces and convective outflow condition was used at the four outlet grilles. Temperature values were specified at the surfaces of inlet grilles, the surgical lamps, 768 heads of the medical staff, patient's head, and patient's knee and all other boundary surfaces were 769 assumed adiabatic. Computations were performed on 1600 processors in parallel and flow statistics involving the time-averaged mean velocity field, turbulence intensity, and temperature distribution were computed. 772

Two computations were performed with the blower-off and blower-on to calculate a three-dimensional, time-dependent flow within the OR. Rising thermal plumes from the warm surfaces of surgeons heads, the patient's knee, patient's head, and the surgical lamp were calculated. With the blower on, air was drawn from the floor of the OR, heated, and blown into a blanket that covers the torso region of the patient. The blanket was covered with a plastic drape. The blower hot air generated forced convective currents and strong thermal plumes that interacted with the ultra-clean ventilation air. For both cases, trajectories of 3 million squames, placed initially on the floor in a small region surrounding the OT and surgeons, were calculated and contrasted to quantify the effect

of the hot air blower. The squames particles were assumed to be spherical in shape with 10 micron diameter and density of liquid water. The particle trajectories were tracked in a Lagrangian frame by computing the drag, lift, and buoyancy forces. The temporal variations of the number of squames particles within four imaginary boxes placed strategically above the two side tables, over the OT, and one surrounding the patient's knee were calculated and contrasted between the blower-off and blower-on cases. The following main conclusions can be drawn from these predictive computations:

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- 1. For the case of blower-off, the ventilation air from the ceiling inlet grilles moves downwards, then is deflected by the surgical lights and the table, impinges on the floor farther away from the OT, and finally exits through the outlet grilles. Large recirculation regions are created on both sides of the table. The flow is not symmetric owing to asymmetries in the configuration of the OR contents. The maximum turbulence intensity level is about 30% in the high shear regions between the inlet air streams and the initial stagnant air in the OR, as well as near the warm surgical lights due to the buoyant plume. It is observed that the buoyant plumes from the patient's knee and other warm surfaces are relatively weak, and do not significantly alter the mean ventilation air flow.
- 2. For the case of blower-on, the mean flow underneath and around the OT is significantly modified and large levels of turbulence intensity are observed under the OT. The turbulence intensity levels are as high as 60% in regions affected by the rising thermal plumes from the blower. The instantaneous temperature contours confirm that the increased turbulence level is mainly because of the thermal plumes from the hot blower air causing higher temperature regions under the OT in comparison with the blower-off case. The flow is also highly asymmetric owing to the orientation and location of the drape. The rising thermal plumes are even observed to reach the ceiling in some regions and the downward ventilation flow from the inlet grilles was modified above the OT which also affected the recirculation region.
- 3. Drastic differences in the trajectories of the squames are observed between the blower-off and blower-on cases. With the blower-off, the majority of the squames are dispersed by the ventilation air flow towards the outlet grilles. None of the squames actually rise to the level of the side tables or the OT. In contrast, with the blower-on, a large number of squames are lifted upwards by the rising thermal plumes. Some of the squames are lifted above the surgeons

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heads and are blown towards the OT by the downward moving ventilation air. Large number of squames are seen to be above the OT, several are surrounding the surgeons hands, above the side tables, and some are very close to the patient's knee and the surgical site. Majority of the squames that come close to the surgical site were found to have originated from the sides parallel to the length of the OT.

4. With the blower off, none of the squames particles were found to enter the four imaginary boxes placed above the side tables, OT, and a region surrounding the patient's knee. Some particles are lifted from the floor over time, but none rise close to the level of the imaginary boxes as the downward flow due to the ventilation air keeps the particles closer to the floor. With the blower turned on, hot air discharged from the edges of the drape and the resultant thermal plumes drag the squames, making them rise upwards. Some of the squames rise above the surgeons heads in the recirculation region on the sides of the OT. These particles are then flushed down onto the OT by the ventilation air from the inlet grilles. Statistically significant particles do enter the imaginary boxes of interest above the operating table and the patient's knee. Few particles are also observed above the side tables.

Starting with the worst-case scenario of having squames on the floor, it was shown that the hot air from the blower and the resultant thermal plumes are capable of lifting the particles and transporting them to the side tables, above the operating table, and the surgical site. It should be emphasized that if we also include the repetitive motion of the surgeons, the motion of medical assistants to fetch the surgical instruments placed on the side tables, and the resulting suspended squames shed by all staff in the OR, then the probability of dispersing the squames to the surgical site will be increased even further.

Although computationally intensive, large-eddy simulation of convective ventilation air flow and hot air from the blower in an OR is necessary to provide reliable predictions of the turbulent flow and dispersion of squames.

835 Appendix A

The aerodynamic behavior of squames suspended in a fluid is in general dependent upon the size and shape of the squames, their density, relative velocity with respect to the fluid motion, and density of 837 the fluid. In the present study, the squames are suspended in air at room temperature (density ρ_g). 838 The human skin cells or squames typically are disc-shaped with a diameter ranging from 4–20μm 839 and a thickness of 3–5 μ m with density close to that of liquid water ($\rho_p = 1000 \text{kg/m}^3$) (Noble et al., 1963; Noble, 1975; Snyder, 2009). 841 Settling of a squame particle depends on its weight, the drag and buoyancy force on the particle, 842 and its orientation relative to the flow direction. Owing to the changes in orientation and also re-843 sultant rotation and torque on disc particles, computing large number of trajectories in a Lagrangian 844 frame is complicated. It is thus easier to assume these particles of spherical shape with an equivalent B45 diameter such that their aerodynamic characteristics are matched. An equivalent diameter of the 846 spherical particle should be calculated by matching the settling velocities for the two shapes. Since $\rho_p/\rho_g = 1000$, the buoyancy force is much smaller compared to the weight of the particle. B48 Then the settling velocity can be obtained from the balance of drag and gravitational forces, B49

$$F_d = F_g. (24)$$

The drag and gravitational forces on a disc-shaped particle are given as,

$$F_d = C_{d,\operatorname{disc}} \frac{1}{2} \rho_g U_{\operatorname{disc}}^2 A_p, \tag{25}$$

$$F_g = (A_p h_{\text{disc}}) \rho_p \mathbf{g}; \ A_p = \frac{\pi}{4} D_{p,\text{disc}}^2$$
 (26)

where U_{disc} is the settling velocity of the disc, $C_{d,disc}$ is the drag coefficient, A_p is the frontal area of the circular disc, g is the gravitational acceleration, $D_{p,\text{disc}}$ is the diameter, and h_{disc} is the thickness of the disc. Equating the drag force to the weight of the disc to obtain the settling velocity as,

$$U_{\rm disc} = \sqrt{2g \left(\frac{\rho_p}{\rho_g}\right) \left(\frac{h_{\rm disc}}{C_{d,\rm disc}}\right)}.$$
 (27)

Following similar procedure, the settling velocity of a sphere of diameter $D_{p,\mathrm{sphere}}$ can be ob-

tained as,

$$U_{\text{sphere}} = \sqrt{\frac{4}{3}g\left(\frac{\rho_p}{\rho_g}\right)\left(\frac{D_{p,\text{sphere}}}{C_{d,\text{sphere}}}\right)},\tag{28}$$

where $C_{d,\text{sphere}}$ is the drag coefficient on a spherical particle. 853

In order to match the aerodynamic performance of the two shapes, the two settling velocities should be the same. Equating U_{disc} and U_{sphere} we get, 855

$$D_{p,\text{sphere}} = \frac{3}{2} h_{\text{disc}} \left(\frac{C_{d,\text{sphere}}}{C_{d,\text{disc}}} \right). \tag{29}$$

For Stokes flow ($Re \le 1$), the drag coefficients are given as (Munson et al., 1990),

$$C_{d,\text{sphere}} = \frac{24}{Re}$$
 (30)
 $C_{d,\text{disc}} = \frac{20.4}{Re}$, flow normal to circular disc (31)
 $= \frac{13.6}{Re}$, flow parallel to circular disc. (32)

$$C_{d,\text{disc}} = \frac{20.4}{Re}$$
, flow normal to circular disc (31)

$$=\frac{13.6}{Re}$$
, flow parallel to circular disc. (32)

Using a disc thickness of $h_{\text{disc}} = 5 \mu \text{ m}$, and using the drag coefficients for the disc and the sphere, 856 equation (29) gives an equivalent spherical diameter in the range of $D_{p,sphere} = 8.78$ and $13.2 \mu m$. Thus, an assumption of 10 micron spherical particle is reasonable to obtain similar dispersion be-858 havior on an average as that of the disc-shaped squames particles. **B59**

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Exhibit 2

Summary of Opinions

I have conducted a computation fluid dynamic simulation of a typical operating room and knee implant surgery procedure. In creating the three-dimensional model of the operating room and its setup, many assumptions were made to reduce the effects of the Bair Hugger patient warming system on disrupting the ventilation air flow. For example, the HVAC system modeled is superior to many, if not all, the HVAC systems used in operating rooms. Similarly, the assumptions made for draping, particle count, position of lights, etc. are all in favor of reducing the disruption caused by the Bair Hugger patient warming system.

Based upon my education, training, experience, and the computation fluid dynamics analysis discussed in Exhibit A, I will offer the following general causation opinions within a reasonable degree of engineering certainty:

- 1. The use of a Bair Hugger Model 750 Blower with the Bair Hugger Upper Body blanket disrupts the turbulent airflow around the operating table.
- 2. The use of a Bair Hugger Model 750 Blower with the Bair Hugger Upper Body blanket significantly increases the particle count over the surgical site, operating table, and side tables.
- 3. The use of a Bair Hugger Model 750 Blower with the Bair Hugger Upper Body blanket significantly reduces the effect of the operating room's HVAC system in protecting the surgical site from contaminants.
- 4. The use of a Bair Hugger Model 505 Blower with the Bair Hugger Upper Body blanket will have the same effects as stated in items 1 through 3 above, but at a reduced temporal rate, i.e. it would take longer time to observe the same effects of BH Model 750.
- 5. The Bair Hugger patient warming system significantly increases the number of contaminants reaching the operating table.

Name : S. E. Elghobashi June 2016

Nationality : U.S.A.

Education:

Degree	$\mathbf{Y}\mathbf{ear}$	Institution
M.Sc. (Mechanical Engineering)	1971	Univ. of Southern California, Los Angeles, USA.
Ph.D. (Mechanical Engineering)	1974	Imperial College, University of London, England.
D.Sc. (Mechanical Engineering)	1999	Imperial College, University of London, England.

Professional Activities (partial list)

Member of the National Academy of Engineering.

Fellow of the American Physical Society.

Fellow of the American Association for the Advancement of Science.

Fellow of the American Society of Mechanical Engineers.

Visiting Fellow of Cambridge University, Wolfson College, England, 1999.

Senior Award of International Conference on Multiphase Flow, Florence, Italy, May 25, 2016.

Chair of the Nominating Committee of American Physical Society, Div. Fluid Dynamics (2014-2015).

Member of Fellowship Committee of American Physical Society, Div. Fluid Dynamics (2009-11).

Member of Science and Engineering Advisory Committee (SETAC) of Blue Waters supercomputer project(2016-2017). https://bluewaters.ncsa.illinois.edu/setac Senior member of the American Institute of Aeronautics and Astronautics(AIAA).

Member of the Combustion Institute.

Member of EuroMech.

Member of the Editorial Advisory Board of International J. of Multiphase Flow(2010-present).

Guest Editor of International J. of Multiphase Flow, Special Issue on Point-particle model for disperse turbulent flows, vol. 35, 2009.

DIC: Diploma of Membership of Imperial College in Mech. Engineering, 1974.

British Science Research Council (SRC) Scholarship (1971-1974).

Major Research Interests

Direct numerical simulation of turbulent flows, including multiphase and chemaically-reacting flows, and biomedical flows.

Research and Professional Experience

March 2015 - Present UC Distinguished Professor, Mechanical and Aerospace Engineering

Department, University of California, Irvine.

July 1985 - Feb. 2014 Professor, Mechanical and Aerospace Engineering Department,

University of California, Irvine.

July 1997 -	June 2002	Chairman, Mechanical and Aerospace Engineering Department,
		University of California, Irvine.
Aug. 1984 -	July 1985	Visiting Scientist, DFVLR, German Aerospace
		Research Establishment, Institute of Atmospheric Physics,
		Oberpfaffenhofen, West Germany (Sabbatical Year).
July 1983 -	July 1984	Vice Chairman, Mechanical Engineering Department,
•	·	University of California, Irvine.
July 1982 -	June 1985	Associate Professor, Mechanical Engineering Department,
-		University of California, Irvine.
July 1978 -	June 1982	Assistant Professor, Mechanical Engineering Department,
		University of California, Irvine.
Jan. 1978 -	June 1978	Staff Research Engineer, Acurex Corporation,
		Aerotherm Division, Mountain View, California.
Oct. 1974 -	Dec. 1977	Group Leader, CHAM, (Concentration, Heat and Momentum),
		London, England and Huntsville, Alabama.
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Reviewer for:

Journal of Fluid Mechanics Physics of Fluids Nature Science Physical review Letters International Journal of Multiphase Flow Journal of Combustion Science and Technology Combustion and Flame Journal of American Institute of Aeronautics and Astronautics Journal of Fluids Engineering Journal of Heat Transfer International Journal of Numerical Heat Transfer International Journal of Heat and Mass Transfer International Journal of Heat and Fluid Flow Progress in Energy and Combustion Science Journal of Applied Mathematical Modeling National Science Foundation NASA Department of Energy University of California Energy Research Group McGraw Hill Book Co.

John Wiley Book Co. and Wiley Interscience Europe.

Consulting

1974 - 1978

NASA- Lewis, NASA- Langley, NASA- Marshall, AFOSR, ARO, ONR

Westinghouse, General Electric, Airesearch ALCAN, ALCOA, Corning, Phillip Morris Ballistic Missile Advance Technology Center Rolls-Royce, England Rheinmetall, Germany Societe National des Poudres et Explosifs, France Spectron Development Labs.

1981 - 1996

Jet Propulsion Laboratory
Ballistic Missile Advance Technology Center
R&D Associates
Physical Research Inc.
P D A Engineering
1978 - 2000
Science Applications Inc.

Invited Keynote and Distinguished Lectures since 2000

- L1. Elghobashi, S. "On the two-fluid and trajectory approaches for DNS of turbulent particle-laden flows", Part 1: DNS of bubble-laden flows via the two-fluid approach, [Invited Lecture] Von Karman Institute for Fluid Dynamics, Rhode-Saint-Genese, Belgium, April 3-7, 2000.
- L2. Elghobashi, S. "On the two-fluid and trajectory approaches for DNS of turbulent particle-laden flows", Part 2: On the approximation of the two-way coupling terms in the trajectory approach, [Invited Lecture] Von Karman Institute for Fluid Dynamics, Rhode-Saint-Genese, Belgium, April 3-7, 2000.
- **L3.** Elghobashi, S. "On the point-force approximation in DNS of prticle-laden turbulent flows with two-way coupling", [Invited lecture] ERCOFTAC Conference on Dynamics of Particle-Laden Flows, Zurich, Switzerland, July 3-5, 2000.
- L4. L4. Elghobashi, S. "Recent Advance in DNS of Particle-Laden Turbulent Flows" [Invited Plenary lecture], XI Congress on Numerical Methods and their Applications, ENIEF 2000, San Carlos de Bariloche, Argentina, November 20-24, 2000.
- L5. L5. Elghobashi, S. "The physical mechanisms of modifying the structure of turbulent homogeneous flows by dispersed particles", [Invited Plenary Lecture], ERCOFTAC Conference on Small Particles in Turbulence, Seville, Spain, March 11-13, 2002.
- L6. S. Elghobashi "On the physical mechanisms of drag reduction in a mirobubble-laden turbulent boundary layer" [Keynote Lecture] at The 5th International Con-

- ference of Multiphase Flow (ICMF 2004), Yokohama, Japan, May 31 June 3, 2004.
- L7. S. Elghobashi "On the drag reduction in a mirobubble-laden spatially-developing turbulent boundary layer", **IUTAM Symposium** on Recent advances in disperse multiphase flow simulation- [Invited Lecture]- Chicago-October 2004.
- L8. S. Elghobashi "Reynolds number effect on drag reduction in a microbubble-laden spatially-developing turb. boundary layer", Euromech Conference on Hydrodynamics of bubbly flows- [Invited Lecture]- Lorentz Center, Leiden, the Netherlands, June 6-8, 2005.
- L9. S. Elghobashi "On drag reduction in a microbubble-laden spatially-developing turbulent boundary layer", European Science Foundation- Challenging Turbulent Lagrangian Dynamics, [Invited Lecture]- Castel Gandolfo, Italy, Sept. 1-4, 2005.
- L10. S. Elghobashi "On drag reduction in a microbubble-laden spatially-developing turbulent boundary layer", Thirteen IUTAM Advanced School & Workshop, Particle Dispersion in Turbulent Flows, [Invited Lecture I] CISM, Udine, Italy, September 12-16, 2005.
- L11. S. Elghobashi "Reynolds number effect on drag reduction in a microbubble-laden spatially-developing turb. boundary layer", Thirteen IUTAM Advanced School & Workshop, Particle Dispersion in Turbulent Flows, [Invited Lecture II]- CISM, Udine, Italy, September 12-16, 2005.
- L12. S. Elghobashi, "Direct simulation of turbulent flows laden with particles or bubbles", CIEMAT: Research Centre for Energy, Environment and Technology, [Invited Lecture], Madrid, Spain, June 21, 2006.
- L13. S. Elghobashi, "DNS of the two-way interactions between dispersed solid particles and turbulent flows", Workshop on multiphase turbulence: Dust storms, erosion, hurricanes and tornadoes, [Invited Lecture], Xian, China, July 16-18, 2007.
- L14. S. Elghobashi, "On the two-way interactions between dispersed solid particles and turbulent flows", European Workshop on Direct and Large-Eddy Simulation, [Keynote Lecture], Trieste, Italy, Sept. 8-10, 2008.
- L15. S. Elghobashi "On the two-way interactions between dispersed particles and turbulent flows", March 2009 Meeting of American Physical Society Pittsburgh, PA. Bulletin of APS, Vol. 54, 209, [Invited Lecture], March 18, 2009.

- L16. S. Elghobashi "The physical mechanisms of two-way interactions between dispersed particles and turbulent flows", Workshop on Clouds and Turbulence Institute for Mathematical Sciences, Imperial College, [Invited Lecture], London, England, March 23-25, 2009.
- L17. S. Elghobashi "How do inertial particles modify isotropic turbulence?" International Workshop-Solving the Riddle of Turbulence: What, Why, and How? Max Planck Institute for Dynamics and Self-Organization, [Invited Lecture], Göttingen, Germany, May 6 May 9, 2009.
- L18. S. Elghobashi "How do inertial particles modify isotropic turbulence?" International Symposium on Turbulence", [Invited Lecture], Peking University, Beijing, China, Sept. 21-25, 2009.
- L19. S. Elghobashi "How do inertial particles modify isotropic turbulence?" 4th Latin-American Workshop on CFD", [Keynote Lecture], Rio de Janiero, Brazil, July 11-14, 2010.
- L20. S. Elghobashi "On turbulence modulation by dispersed inertial particles" 13th European Turbulence Conference, ETC 13, [Keynote Lecture] University of Warsaw, Poland, September 12-15, 2011.
- L21. F. Lucci, V.S. Lvov, A. Ferrante and S. Elghobashi, "Eulerian-Lagrangian bridge for the energy and dissipation spectra in homogeneous turbulence", [Invited Lecture], International Workshop on "Lagrange versus Euler for turbulent flows", Wolfgang Pauli Institute, Vienna, Austria, May 7-12, 2012.
- **L22.** S. Elghobashi "On the multi-way interactions between turbulent flows and suspended sediment"

International symposium on two-phase modeling for sediment dynamics in geophysical flows(THESIS-2013) [Keynote Lecture] Chatou, Paris, France, June 10-12, 2013.

- **L23.** S. Elghobashi "On the multi-way interactions between turbulent flows and suspended particles"
- Fluid-Mediated Particle Transport in Geophysical Flows (GEOFLOWS13), Kavli Institute for Theoretical Physics [Invited Lecture] UCSB, Santa Barbara, California, December 10, 2013.
- L24. S. Elghobashi "Modulation of isotropic turbulence by dispersed particles," Huazhong University of Science and Technology, Wuhan, China, June 9, 2014. [Plenary Lecture].
- L25. S. Elghobashi "Homogeneous shear turbulence modulation by dispersed small

- particles," Huazhong University of Science and Technology, Wuhan, China, June 10, 2014. [keynote Lecture].
- L26. S. Elghobashi "Modulation of isotropic turbulence by finite-size particles," Huazhong University of Science and Technology, Wuhan, China, June 11, 2014. [keynote Lecture].
- **L27.** S. Elghobashi "How do dispersed inertial particles modify turbulent flows," Department of Mechanics and Engineering Science, **Peking University**, China, June 17, 2014. [Distinguished lecture].
- L28. S. Elghobashi "How do dispersed inertial particles modify turbulent flows," Center for Turbulence Research, Stanford University, July 25, 2014. [Distinguished lecture].
- **L29.** S. Elghobashi "How do dispersed inertial particles modify turbulent flows," Computational and Applied Mathematics, **Pennsylvania State University**, October 10, 2014. [Distinguished lecture].
- L30. S. Elghobashi "How do dispersed inertial particles modify turbulent flows," Aerospace Engineering department, University of Minnesota, April 21, 2015. [Distinguished lecture].
- L31. S. Elghobashi "How do dispersed inertial particles modify turbulent flows," Mechanical Engineering department, Northwestern University, February 1, 2016. [Distinguished lecture].
- L32. S. Elghobashi "How do dispersed inertial particles modify turbulent flows," Mechanical Engineering department, MIT, February 3, 2016. [Distinguished lecture].

Publications

Articles in Books

- B1 Elghobashi, S.E., "Studies in the Prediction of Turbulent Diffusion Flames", Studies in Convection, Vol. 2, B.E. Launder, ed., Academic Press, London, (1977).
- B2 Elghobashi, S. E., and Nomura, K.N., "Direct Simulation of a Passive Diffusion Flame in Sheared and Unsheared Homogeneous Turbulence", **Turbulent Shear Flows 7**, pp. 313-329, W.C. Reynolds, ed., Springer-Verlag, (1991).
- B3 Elghobashi, S. E. "Direct Simulation of turbulent flows laden with dispersed particles", **Handbook on Multiphase Flow**, pp. 13-34:13-60, C. Crowe, ed., CRC, (2005).
- B4 Elghobashi, S. E. "An updated classification map of particle-laden turbulent flows", **Proceedings of IUTAM Symposium on Computational approaches to mul-**, **tiphase flow**, Springer pp. 3-10, , (2006).
- B5 Loy, A.C., Jing, J., Zhang, J., Wang., Y., Elghobashi, S., Chen, Z. and Wong, B.J.F. "Anatomic optical coherence tomography of upper airways", **Optical Coherence Tomography: Technology and Applications**, Ed. W. Drexler and J. Fujimoto, Springer, Chapter 75, pp. 1145-2262, (2015).

Guest Editor

Elghobashi, S.E. "Point-Particle Models for Disperse Turbulent Flows", **International Journal of Multiphase Flow, Special Issue**, Volume 35, Issue 9, Pages 791-878, (September 2009).

Journal Papers

- J1 Elghobashi, S.E., Pun, W.M. and Spalding, D.B., "Concentration Fluctuations in Isothermal Turbulent Confined Coaxial Jets",
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- J2 Elghobashi, S.E. and Wassel, A.T., "The Effect of Turbulent Heat Transfer on the Propagation of an Optical Beam Across Supersonic Boundary and Free Shear Layers",
- Int. J. Heat and Mass Transfer, Vol. 23,pp.1229-1241 (1980).
- J3 Elghobashi, S.E., Samuelsen, G.S., Wuerer, J.E., and LaRue, J.C., "Prediction and Measurement of Mass, Heat and Momentum Transport in a Nonreacting Turbulent Flow of a Jet in an Opposing Stream",
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- J4 Megahed, I.E.A. and Elghobashi, S.E., "On the Numerical Solution of Indeterminate Steady Elliptic Flows",
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- J5 Elghobashi, S.E. and Megahed, I.E.A., "Mass and Momentum Transport in a Laminar Isothermal Two-Phase Round Jet",
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- J6 Elghobashi, S.E. and Abou Arab, T.W., "A Two-Equation Turbulence Model for Two-Phase Flows",
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- J7 Elghobashi, S.E. and Launder, B.E., "Turbulent Time Scales and the Dissipation Rate of Temperature Variance in the Thermal Mixing", Physics of Fluids, Vol. 26, pp. 2415-2419 (1983).
- J8 Modarress, D., Tan, H. and Elghobashi, S.E., "Two-Component LDA Measurement in a Two-Phase Turbulent Jet", AIAA J. Vol. 22, pp. 624-630 (1984).
- J9 Modarress, D., Wuerer, J. and Elghobashi, S.E., "An Experimental Study of a Turbulent Round Two-Phase Jet", Chemical Engineering Communications, Vol. 28, pp. 341-354 (1984).
- ${f J10}$ Wassel, A.T. and Elghobashi, S.E., "Mathematical Simulation of Ocean Thermal Energy Conversion Sea Water Systems",
- J. Solar Energy Engineering Vol. 106, pp. 198-205 (1984).
- J11 Mostafa A.A. and Elghobashi, S.E., "A Study of the Motion of Vaporizing Droplets in a Turbulent Flow",
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- J12 Elghobashi, S.E., Abou-Arab, T., Rizk, M. and Mostafa, A., "Prediction of the Particle-Laden Jet with a Two-Equation Turbulence Model", Int. J. of Multiphase Flow, Vol. 10, pp. 697-710 (1984).
- J13 Bellan J., and Elghobashi, S.E., "Fuel Composition Effects on High Temperature Corrosion in Boiler and Furnaces",
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- J14 Rizk, M., and Elghobashi, S.E., "Wall Effects on the Motion of a Spherical Particle Suspended in a Turbulent Flow",
- Physics of Fluids, Vol. 28, pp. 806-817 (1985).
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neous scalar in isotropic and homogeneous sheared turbulence", **Physics of Fluids**, vol. 4, pp. 606-625 (1992).

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- J26 Nomura, K.N.,and Elghobashi, S. E. " The structure of inhomogeneous turbulence in variable density nonpremixed flames",

Theoretical and Computational Fluid Dynamics, vol. 5, pp. 153-176 (1993).

J27 Elghobashi, S. E., and Truesdell, G.C., "On the two-way interaction between homogeneous turbulence and dispersed solid particles; Part 1: turbulence modification".

Physics of Fluids, vol. A5, pp. 1790-1801 (1993).

- J28 Elghobashi, S. E., 'On Predicting Particle-Laden Turbulent Flows',
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- J29 Truesdell, G.C., and Elghobashi, S. E." On the two-way interaction between homogeneous turbulence and dispersed solid particles; Part 2: particle dispersion", Physics of Fluids, Vol. 6, pp. 1405-1407 (1994).
- J30 Kim, I., Elghobashi, S. E., and Sirignano, W. "Unsteady flow interactions between an advected cylindrical vortex tube and a spherical particle",
 J. Fluid Mechanics, Vol. 288, pp. 123-155 (1995).
- J31 Boratav, O., Elghobashi, S. E., and Zhong, R. "On the alignment of the α -strain and vorticity in turbulent nonpremixed flames", **Physics of Fluids**, Vol. 8, pp. 2251-2253 (1996).
- J32 Kim, I., Elghobashi, S. E., and Sirignano, W. "Unsteady flow interactions between a pair of advected vortex tubes and a rigid sphere", International J. Multiphase Flow, Vol. 23, pp. 1-23 (1997).
- J33 Druzhinin, O. and Elghobashi, S., 'DNS of bubble-laden turbulent flows using the two-fluid formulation', Physics of Fluids, Vol. 10, pp. 685-697 (1998).
- J34 Kim, I., Elghobashi, S. E., and Sirignano, W. 'On the equation for spherical particle motion: effects of Reynolds and acceleration numbers', J. Fluid Mechanics, Vol. 367, pp. 221-253 (1998).
- J35 Boratav, O., Elghobashi, S. E., and Zhong, R.' On the alignment of strain,

vorticity and scalar gradient in turbulent, buoyant, nonpremixed flames', **Physics of Fluids**, Vol. 10, pp. 2260-2267 (1998).

J36 Druzhinin, O. and Elghobashi, S., 'On the decay rate of isotropic turbulence laden with microparticles',

Physics of Fluids, Vol. 11, pp. 602-610 (1999).

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- J38 Elghobashi, S. E., Zhong, R. and Boratav, O. 'Effects of gravity on turbulent nonpremixed flames',

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Physics of Fluids, Vol. 12, pp. 2091-2100 (2000).

- J40 Ahmed, A.M. and Elghobashi, S. E. On the mechanisms of modifying the structure of turbulent homogeneous shear flows by dispersed particles, **Physics of Fluids**, Vol. 12, pp. 2906-2930 (2000).
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- J42 Ahmed, A.M. and Elghobashi, S. E. Direct numerical simulation of particle dispersion in homogeneous turbulent shear flows, Physics of Fluids, Vol. 13, pp. 3346-3364 (2001).
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- J44 Ferrante, A. and Elghobashi, S. E., 'A robust method for generating inflow conditions for direct simulations of spatially-developing turbulent boundary layers', J. Computational Physics, Vol. 198, pp. 372-387 (2004).
- J45 Latz, M. I., Juhl, A. R., Ahmed, A.M., Elghobashi, S. and Rohr, J. 'Hydrodynamic stimulation of dinoflagellate bioluminescence: A computational and experimental study',
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- J47 Ferrante, A. and Elghobashi, S. E., Adams P., Valenciano M. and Longmire D. 'Evolution of quasi-streamwise vortex tubes and wall-streaks in a microbubble-laden turbulent boundary layer over a flat plate', **Physics of Fluids**, Vol. 16(9), pp. S2 (2004).
- J48 Ferrante, A. and Elghobashi, S. E., 'Reynolds number effect on drag reduction in a microbubble-laden spatially-developing turbulent boundary layer', J. Fluid Mechanics, Vol. 543, pp. 93-106 (2005).
- J49 Ferrante, A. and Elghobashi, S. E., 'On the effects of microbubbles on the Taylor-Green vortex flow',
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- J50 Ferrante, A. and Elghobashi, S. E., 'On the accuracy of the two-fluid formulation in DNS of bubble-laden turbulent boundary layers', **Physics of Fluids**, Vol. 19, 045105, pp.1-8 (2007).
- J51 L'vov, V.S., Pomyalov, A., Ferrante, A. and Elghobashi, S. E., 'Analytical model of the time Developing turbulent boundary layer', J. Exp. Theor. Phys., Vol. 86, issue 2, pp. 111-116 (2007).
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- J53 Lucci, F., Ferrante, A. and Elghobashi, S. 'Is Stokes number an appropriate indicator of turbulence modulation by large particles?'

 Physics of Fluids, Vol. 23, pp. 25101-1-7 (2011).
- J54 Cleckler, J., Elghobashi, S. and Liu, F. 'On the motion of inertial particles by sound waves'

 Physics of Fluids, Vol. 24, 033301 (2012).
- Lucci, F., L'Vov, V., Ferrante, A., Rosso, M. and Elghobashi, S., 'Eulerian-Lagrangian bridge for the energy and dissipation spectra in isotropic turbulence', **Theoretical and Computational Fluid Dynamics**, DOI: 10.1007/s00162-013-0310-5(2013).
- J56 Wang, Y. and Elghobashi, S., 'On locating the obstruction in the upper

airway via numerical simulation ',

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- J57 Mylavarapu, G., Wang, Y., Elghobashi, S. and Gutmark, E. 'PIV measurements and numerical simulations of the flow in a human upper airway phantom', Biomechanics and Modeling in Mechanobiology, submitted (2016).

Archival Conference Papers

- C1 Elghobashi, S.E. and Pun, W.M., "A Theoretical and Experimental Study of Turbulent Diffusion Flames in Cylindrical Furnaces", **Proceedings of Fifteenth Symposium (International) on Combustion**, (1974).
- C2 Elghobashi, S.E., Pratt, D.T., Spalding, D.B. and Srivatsa, S.K., "Unsteady Combustion of Fuel Spray in Jet Engine Afterburners", Proceedings of Third International Symposium on Air Breathing Engines, Munich (1976).
- C3 Elghobashi, S.E. and Launder, B.E., "Modeling the Dissipation Rate of Scalar Fluctuations in a Thermal Mixing Layer", **Proceedings of Third Symposium on Turbulent Shear Flows**, (1981).
- C4 Elghobashi, S.E. and Abou Arab, T.W., "A Second Order Turbulence Model for Two-Phase Flows", Proceedings of Seventh International Heat Transfer Conference, Munich (1982).
- C5 Elghobashi, S.E. and Prud'homme, M., "On the Accuracy and Stability of Quadratic Upstream Differencing in Laminar Elliptic Flows", Numerical Methods in Laminar and Turbulent Flow, ed. Taylor, C., Johnson, J., and Smith, W., Pineridge Press, U.K., pp. 317-327 (1983).
- C6 Mostafa A.A. and Elghobashi, S.E., "A Study of the Motion of Vaporizing Droplets in a Turbulent Flow", Proceedings of Ninth International Colloquium and Dynamics of Explosions and Reactive Systems, Poitiers, France, July (1983).
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- C9 Prud'homme, M. and Elghobashi, S.E., "Prediction of Wall-Bounded Turbulent Flows with an Improved Version of a Reynolds-Stress Model", **Proceedings of Fourth International Symposium on Turbulent Shear Flows**, Karlsruhe, Germany, Sept. (1983).
- C10 Elghobashi, S.E. and J.C. LaRue, "The Effect of Mechanical Strain on the Dissipation Rate of a Scalar Variance", Proceedings of Fourth International Sym-

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- C19 Kim, I., Elghobashi, S. E., and Sirignano, W. "Three-dimensional droplet interactions in dense sprays", Paper no 91-0073, AIAA 30th Aerospace Science Meeting, Reno, Nevada, January (1991).
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"How do dispersed inertial particles modify turbulent flows?" University of California, San Diego, Mechanical and Aerospace Engineering Dept., June 3, 2013.

"Direct numerical simulation of the flow in the upper airway via lattice Boltzmann method" National Institute of Health, Bethesda, MD, April 29, 2013.

"On the physical mechanisms of drag reduction in a spatially-developing turbulent boundary layer laden with microbubbles" École Normal Supérieur, Paris, France, March 17, 2011.

"Direct numerical simulation of the flow in the upper airway via lattice Boltzmann method" National Institute of Health, Bethesda, MD, Feb. 24, 2011.

"Turbulence modulation by dispersed inertial particles" Mech. Eng. Dept., Univ. of California, Berkeley, February 11, 2011.

"On the two-way interactions between dispersed particles and turbulent flows" School of Engineering and Mathematical Sciences, City University, London, England, March 26, 2009.

"On the effects of finite-size solid particles on decaying isotropic turbulence", Institut de Mècanique des Fluides de Toulouse, IMFT, Toulouse, France, June 28, 2007.

"On the physical mechanisms of drag reduction in a spatially-developing turbulent boundary layer laden with microbubbles" **Ecole Polytechnique**, The Hydrodynamics Laboratory (LadHyX), **Palaiseau**, **France**, June 26, 2007.

"Turbulence modification in flows laden with particles or bubbles"

The Johns Hopkins University, Mechanical Engineering Department, February 15, 2007.

"Direct simulation of turbulent flows laden with particles or bubbles", Invited Lecture, CIEMAT: Research Centre for Energy, Environment and Technology, Madrid, Spain, June 21, 2006.

"On drag reduction in a spatially-developing turbulent boundary layer laden with microbubbles", **Department of Mechanics and Aeronautics**, **University of Rome** "La Sapienza", Rome,, Italy, September 5, 2005.

"On the drag reduction in a mirobubble-laden spatially-developing turbulent boundary

- layer," School of Mechanical and Aerospace Engineering, Center for Turbulence and Flow Control Research, Seoul National University, Seoul, South Korea, May 27, 2005.
- "On the physical mechanisms of drag reduction in a mirobubble-laden turbulent boundary layer", Department of Mechanical Engineering, University of Tokyo, Japan, June 7, 2004.
- "On the physical mechanisms of drag reduction in a spatially-developing turbulent boundary layer laden with microbubbles", Mech. Eng. Dept., Univ. California, Santa Barbara, California, February 14, 2004.
- "Recent advances in DNS of particle-laden turbulent flows", Institute for Scientific Computing Research, Lawrence Livermore Research Laboratory, Livermore, California, August 7, 2003.
- "DNS of turbulent flows laden with particles", Institute for Scientific Computing Research, Lawrence Livermore Research Laboratory, Livermore, California, March 27, 2003.
- "On the physical mechanisms of modifying the structure of turbulent homogeneous shear flows by dispersed particles", Mechanical Engineering Dept., Stanford University, Stanford, California, October 30, 2001.
- "Recent Advances in DNS of Turbulent Flows Laden with Particles, Droplets or Bubbles", Universite Pierre et Marie Curie, Paris, France, September 19, 2001.
- "Recent advances in direct numerical simulations (DNS) of turbulent shear flows laden with particles", Institute for Scientific Computing Research, Lawrence Livermore Research Laboratory, Livermore, California, May 4, 2001.
- "Recent Advances in DNS of Turbulent Flows Laden with Particles, Droplets or Bubbles", The Aerospace Corporation, Los Angeles, California, April 17, 2001.
- "Recent advances in direct numerical simulations (DNS) of turbulent shear flows laden with particles", Institute for Scientific Computing Research, Lawrence Livermore Research Laboratory, Livermore, California, May 4, 2001.
- " On the physical mechanisms of modifying the structure of turbulent homogeneous shear flows by dispersed particles", ETH, Zürich, Switzerland, October 4, 2000.
- "Recent advances in direct numerical simulations (DNS) of turbulent shear flows laden with particles", Paul Scherer Institute, Villigen, Switzerland, October 3, 2000.

- " Recent advances in direct numerical simulations (DNS) of turbulent shear flows laden with particles and bubbles", Mechanical Engineering Department, Imperial College, London, April 6, 2000.
- "Recent advances in direct numerical simulations (DNS) of turbulent shear flows laden with particles and bubbles", Mechanical and Aerospace Engineering Department, Univ. California, San Diego, March 15, 2000.
- "Direct numerical simulation of particle-laden flows: the trajectory and two-fluid approaches", Dept. of Mechanical Engineering, Univ. of Illinois, Urbana-Champaign, November 9, 1999.
- " Evolution of flame surface in buoyant and nonbuoyant turbulent nonpremixed reactions", Graduate Aeronautical Laboratories, California Institute of Technology, January 16, 1998.
- "How do particles modify the turbulence energy in a homogeneous shear flow?", **Department of Chemical Engineering**, Univ. of California, Santa Barbara, April 16, 1997.
- "Direct numerical simulation of particle-laden homogeneous turbulent shear flows", CEA: Atomic Energy Commision Military Applications Division, Bordeaux, France, April 2, 1997.
- "Mathematical models of particle-laden flows", CEA: Atomic Energy Commision Military Applications Division, Bordeaux, France, April 2, 1997.
- " DNS of surface topology of turbulent nonpremixed flames", **CEA**: Atomic Energy Commision Military Applications Division, Bordeaux, France, April 2, 1997.
- "Effects of buoyancy on turbulent diffusion flames", Dept. of Mechanical Engineering, Yale University, June 10, 1996.
- "Particle dispersion and turbulence modification in a homogeneous shear flow", Dept. of Mechanical Engineering, California Institute of Technology, April 23, 1996.
- "Particle dispersion and turbulence modulation in a homogeneous shear flow", Aerospace Engineering Dept., University of Southern California, October 4, (1995).
- " DNS of particle dispersion in homogeneous shear turbulence" Institut de Mecanique des Fluides de Toulouse, Toulouse, France, September 12, (1995).
- " DNS of a turbulent diffusion flame under different gravity conditions" Institut de Mecanique des Fluides de Toulouse, Toulouse, France, September 12, (1995).

- "DNS of particle dispersion in homogeneous shear turbulence" **Technical University** of Delft, Delft, Netherlands, September 7, (1995).
- "DNS of a turbulent diffusion flame under different gravity conditions" **Technical University of Delft, Delft, Netherlands**, September 7, (1995).
- "On the two-way interaction between homogeneous turbulence and dispersed solid particles", Naval Command, Control and Ocean Surveillance Center, San Diego, CA, Oct. 19, 1993.
- "On the two-way interaction between homogeneous turbulence and dispersed solid particles", Arizona State University, Tempe, Arizona, Oct. 8, 1993.
- "Direct numerical simulation of particle dispersion and turbulence modulation in homogeneous turbulence", NATO Advanced Research Workshop on Chaotic Advection, Tracer Dynamics, and Turbulent Dispersion, Alessandria, Italy, May 24-28, 1993.
- "On predicting particle-laden turbulent flows", Workshop on turbulence in particulate multiphase flow, Fluid Dynamics Laboratory, Battelle Pacific Northwest Laboratory, Richland, WA, March 22, 1993.
- "On the two-way interaction between homogeneous turbulence and dispersed solid particles", AMES Dept. Univ. of California, San Diego, February 5, 1993.
- "On the two-way interaction between homogeneous turbulence and dispersed solid particles", NASA Langley Research Center, December 14, 1992.
- "On the modification of energy spectrum of homogeneous turbulence by dispersed solid particles", Department of Mathematics, UCI, May 21, 1992.
- "The two-way coupling between solid particles and homogeneous decaying turbulence", Mechanical and Aerospace Engineering Department, Princeton University, August 23, 1991.
- " Direct simulation of particle-laden homogeneous turbulence", Los Alamos National Laboratory, May 25, 1991.
- "The effect of turbulence on the propagation of an electromagnetic wave in a compressible turbulent boundary layer", Workshop on Aerothermal Technology Development, U.S. Strategic Defense Command, Huntsville, Alabama, June 13, 1991.
- "Direct numerical simulation and closure modelling of particle-laden turbulent flows", Workshop on Turbulence Simulation and Modelling, NASA-Marshall, Huntsville,

Alabama, April 14-15, 1991.

- "Direct numerical simulation of particle dispersion in sheared and unsheared homogeneous turbulence", Mechanical Engineeing Department, University of Southern California, March 1, 1990.
- "Direct numerical simulation and modelling of particle-laden turbulent flows", German Aerospace Organization (DLR), Munich, Germany, December 4,1989.
- "Direct numerical simulation of particle dispersion in homogeneous turbulent flows", University of Kaiserslautern, West Germany, December 5,1989.
- "Direct numerical simulation of particle dispersion in isotropic and sheared turbulent flows", Institut de Mecanique des Fluides, Toulouse, France, December 6,1989.
- "Direct numerical simulation of particle dispersion in homogeneous turbulent flows", University of Rouen, France, December 7,1989.
- "Direct numerical simulation and modelling of particle-laden turbulent flows", Shell Conference on Computational Fluid Dynamics, Apeldoorn, The Netherlands, December 11,1989.
- "Direct numerical simulation of particle dispersion in homogeneous turbulent flows", Norway Institute of Technology, Trondheim, Norway, December 15,1989.
- "Direct numerical simulation of particle dispersion in grid-generated turbulence", Workshop on droplets and sprays, AFOSR and ONR Contractors Meeting, Ann Arbor, Michigan, June 21,1989.
- "Direct numerical simulation of particle dispersion and chemical reaction in turbulent flows", G.M. Research Laboratory, Thermal Science Department, Warren, Michigan, June 22,1989.
- "Direct numerical simulation of stratified turbulent homogeneous shear flow", Idaho National Engineering Laboratory, Idaho Falls, September 8,1988.
- "Direct numerical simulation of stratified turbulent homogeneous shear flow", Center for Microgravity and Materials Research, University of Alabama, Huntsville, August 5, 1988.
- "Direct simulation of stable stratified turbulent homogeneous shear flows", Third International Symposium on Stratified Flows, California Institute of Technology, February 3-5, 1987.

- "Direct simulation of the passive-scalar mixing layer", Institut de Mecanique des Fluides, Toulouse, France, September 11, 1987.
- "Direct simulation of stratified homogeneous turbulent shear flow", **Department of Aerospace Engineering, University of Southern California**, October 8, 1986.
- "Direct simulation of stratified homogeneous turbulent shear flow", Institut de Mecanique Statistique de la Turbulence, Marseille, France, October 22, 1986.
- "Direct simulation of homogeneous turbulent shear flow", Mechanical Engineering Department, University of California, Irvine, July 22, 1986.
- "Direct simulation of stratified homogeneous turbulent shear flow", AMES Department, University of California, San Diego, February 3, 1986.
- "Direct simulation of turbulent shear flow with buoyancy", Jet Propulsion Laboratory, California Institute of Technology, May 30, 1986.
- "Direct numerical simulation of a turbulent homogeneous shear flow with buoyancy", Mechanical Engineering Dept., University of California, Irvine, October 18, 1985.
- "Direct simulation of turbulent homogeneous shear flow", **DFVLR**, **Institute of Atmospheric Physics**, **Oberpfaffenhofen**, **West Germany**, June 21, 1985.
- "Prediction of the turbulent jet laden with vaporizing droplets" **Dept. of Fluid Mechanics**, **University of Erlangen**, **West Germany**, May 22,1985.
- "Experimental study of the turbulent jet laden with particles", University of the German Armed Forces, Aerospace Department, Munich, West Germany, February 7,1985.
- "Measurement and prediction of the turbulent two-phase jet", University of Karlsruhe, Mechanical Engineering Dept., December 13,1984.
- "Prediction of the turbulent jet laden with solid spherical particles", DFVLR, Institute of Atmospheric Physics, Oberpfaffenhofen, West Germany, December 5, 1984.
- "Recent developments in mathematical modeling of dispersed two- phase flows", presented at the Mechanical Engineering Dept., Technical University of Munich, West Germany, November 27,1984.

- "Recent developments in mathematical modeling of dispersed two- phase flows", presented at the Mechanical Engineering Dept., University of California, Berkeley, March 20, 1984.
- "Effects of dispersed two-phase flows on turbulence structure", Office National d'Etudes et de Recherches Aerospatiales (ONERA), Paris, France, September 19, 1983.
- "Turbulence modulation in a turbulent two-phase jet: theory and experiment", Mechanical Engineering Department, University of Kaiserslautern, West Germany, September 16, 1983.
- "Passive-scalar time-scales in turbulent flows", DFVLR, Institute of Atmospheric Physics, Oberpfaffenhofen, West Germany, September 15, 1983.
- "Mathematical models of temperature variance and time-scales for the thermal mixing layer", Institut de Mecanique Statistique de la Turbulence, Marseille, France, July 8, 1983.
- "Experimental and theoretical study of dispersed two-phase turbulent jets", Institut de Mecanique des Fluides, Toulouse, France, July 6, 1983.

EXHIBIT DX37

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates to All Actions

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EXPERT REPORT OF MICHAEL W. BUCK

I. SUMMARY OF QUALIFICATIONS & EXPERIENCE

A. Education and Training

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My education and training have been focused on biology. I received a Bachelor of Arts in Biology, with Concentrations in Physical Science, Chemistry, Economics, and Psychology from Minot State University in 1989. I nearly completed a Master's Degree in Public Health in Industrial Hygiene at the University of Minnesota (39 graduate credits completed).

I have two recent publications: Chapter 5: Air Monitoring for Quality Evaluation in Healthcare, APIC 2015 INFECTION PREVENTION MANUAL FOR CONSTRUCTION AND RENOVATION, and DISPLACEMENT VENTILATION AS A VIABLE AIR SOLUTION FOR HOSPITAL PATIENT ROOMS (2010). Since 2003, I have provided presentations at various conferences on issues relating to industrial hygiene in the healthcare setting.

I have the following current certifications: Asbestos Contractor Supervisor Training certified by the Minnesota Department of Health (MDH):; Recognition of Indoor Air Quality Issues from the Midwest Center for Occupational Health and Safety; Introduction to Food and Air-Borne Fungi certification from the Centraal bureau voor Schimmelcultures Institute of the Royal Academy of Arts and Sciences at the University of Ottawa; Applied Thermographer – Infrared Technology certification from Restoration Consultants; NIOSH 582 – Asbestos Air Analysis certification from Delta Environmental Consultants; Building Inspector Hazardous

Materials; Asbestos Abatement Site Supervisor. In the past I have been certified as an OSHA 501 Certified Trainer; an Asbestos Project Designer; a Lead Risk Assessor, and a Lead Inspector. A copy of my Curriculum Vitae is attached as Exhibit A.

B. Experience

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For over 25 years, I have worked in the Department of Environmental Health and Safety at the University of Minnesota. For over seventeen years, I have been an Environmental Health and Safety Compliance Specialist in the Department of Environmental Health and Safety at the University of Minnesota. capacity I have been responsible for conducting indoor air quality investigations, and have coordinated remediation activities. I am responsible for coordinating sample collection from the University Hospital's anesthetic gas employee exposure program, I manage the Departments' Micro Lab (including sample tracking and analysis), and I repair and maintain the Department air quality sampling equipment. Part of my current duties include review of various construction plans and evaluation of IAO concerns. In addition, I audit the Facilities Management Hazardous Material Program, and work with outside contractors on abatement projects. From 1991 – 2000, I was a Principal Safety Technician in the Department of Environmental Health and Safety at the University of Minnesota, where my principal responsibilities included conducting building hazard assessments, as well as identifying and supervising asbestos identification and abatement projects.

C. Medical/Legal Work Experience

Over the past ten years, I have been retained as an expert consultant on issues relating to hospital certification of critical care environments, including the BMT (Bone Marrow Transplant), ICU (Intensive Care Unit), NICU (Neonatal Intensive Care Unit), and OR (Operating Room), ventilation systems, and air and surface sampling. In my capacity as a consultant I have provided training on HVAC mechanics, as well as water infiltration remediation measures to various building managers. I have also provided consulting on industrial hygiene issues to real estate property management companies. As a consultant, my time is billed at \$200/hour, \$3,000 per day for deposition testimony, and \$6,000 per day for trial testimony. I have provided no testimony by way of deposition and/or trial over the past four years.

II. QUESTION PRESENTED

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I was retained to evaluate whether or not the Bair Hugger Forced Air Warming System generates and/or omits particles.

III. METHODOLOGY & METHODS

A. Methodology and Approach to Test for Potential Particles

Healthcare professionals and facilities care deeply about particles, as particles can transmit pathogens. Particles themselves can be extremely small. By way of example, Figure 1, below, shows the size of various pathogens, including

bacteria. As illustrated in Figure 1, the vast majority of bacteria range in size from .3 to 1.2 microns. To provide additional context, Figure 2 illustrates how "big" a micron is, by showing a grain of salt (60 μ m), dust mite waste (20 μ m), and staphylococcus aureus (0.9 μ m), each placed upon a cross section of a human hair (which has a diameter of 100 μ m) to show scale.

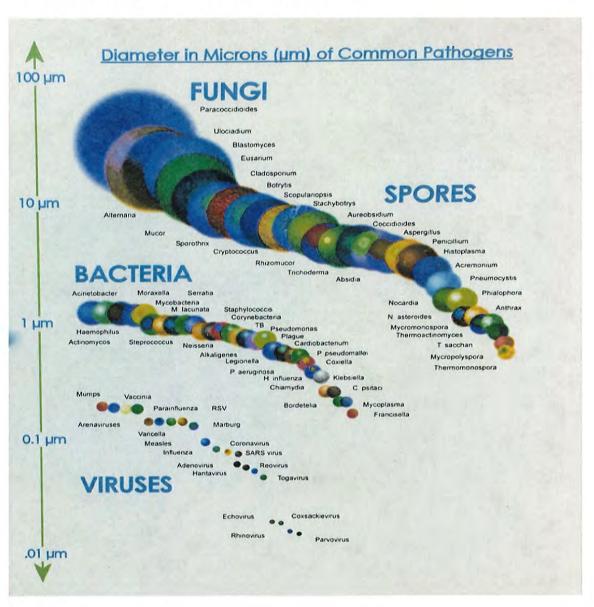


Figure 1

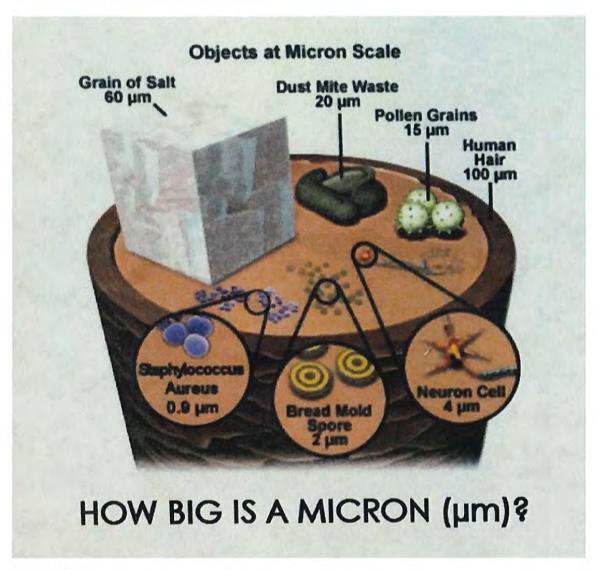


Figure 2

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Because these particles are so small, specialized instrumentation is required to identify, measure and quantify them. The experiments discussed in this report were conducted in a cleanroom, using a particle counter.

A cleanroom or clean room is an environment, typically used in manufacturing, including of pharmaceutical products or scientific research. The cleanroom can be used to evaluate the source of particles. For example, a device such as a bubbling humidifier can be placed in the room and with manipulation of

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airflow create an environment of droplet nuclei when saline is aerosolized. A comparison between particles generated by bubbling versus evaporation changed the way we deliver humidified air to patients. A filtered device that blows air can and should be evaluated in a clean room environment in the same manner to determine the difference – if any – with the applicable filter in place and with the applicable filter removed. This is considered an assessment of the *efficiency* of the filter.

A particle counter is a portable instrument that measures and reports air contamination. The particles can be differentiated into respective particle sizes using laser and optics to count sizes per unit volume of air. When the investigation includes air quality analysis, comparison data is useful to determine particle generation differences in mode of operation, location of filtration or difference in controls. For example what percentage reduction is observed from breathing zone particle sizes before and after using filtration for supplying air to a device. The experiments outlined below used a Fluke model 983 particle counter.

B. Material and Methods for Testing Bair Hugger Devices

1. Tests on the Machines

The Bair Hugger model units (1 used 750 series and 1 new 775 series) and its component parts (including the blower, filter, hose, and disposable blanket) were studied and evaluated to determine the number and size of any particles generated by the unit itself through normal operating procedures. This evaluation

was completed with a used Bair Hugger Model 750, and new Bair Hugger Model 775. The filter efficiency was also evaluated by removing filter media and comparing and contrasting the number and size of particles recorded with the filter in-line versus when the filter was removed and the machine run without the filter in place.

The first evaluation was carried out in a HEPA filtered (99.97% for .3µm sized particles) clean room using a laser optical particle counter that recorded differential particle sizes ranging from 0.3µ up to greater than 10µ in size. The particle counter isokinetic probe was mounted inside the Bair Hugger air supply hose with the Bair Hugger blower placed on the floor of the clean room.

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The Bair Hugger was evaluated using normal operating modes (ambient

¹ Both Bair Hugger devices were Model 750, provided by MDL Plaintiffs' Counsel.

23°C, 38°C, 43°C, and blower unit on its side) to establish the initial discharge of air (particles) from the end of the air supply hose.





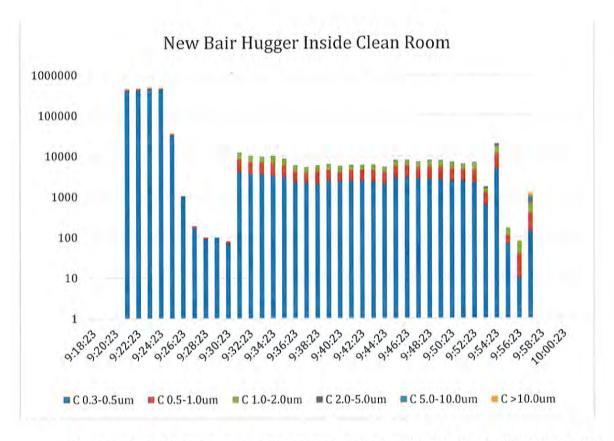


The evaluation of the air discharge was carried out through each operational mode and particle counts were collected at one minute intervals continuously through the end of the evaluation to validate air quality content of the Bair Hugger tested. This evaluation was completed with both a used Bair Hugger 750 and unused Bair Hugger model 775. These evaluations showed particles coming out of both the new and the used Bair Hugger devices.

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A second evaluation was also carried out in a HEPA filtered (99.97% for .3μm sized particles) clean room using a particle counter that recorded differential particle sizes ranging from .3μ up to greater than 10μ in size. The particle counter isokinetic probe was mounted inside the Bair Hugger air supply hose which was placed inside the clean room to discharge. The Bair Hugger blower was placed outside the clean room on the floor. The Bair Hugger was evaluated using normal operating modes (ambient 23°C, 38°C, filter out, and filter in) to establish the initial discharge of air (particles) from the end of the air supply hose. The evaluation of the air discharge was carried out through each operational mode and particle counts were collected at one minute continuous intervals to validate air quality content and filter efficiency of the Bair Hugger tested. This evaluation was

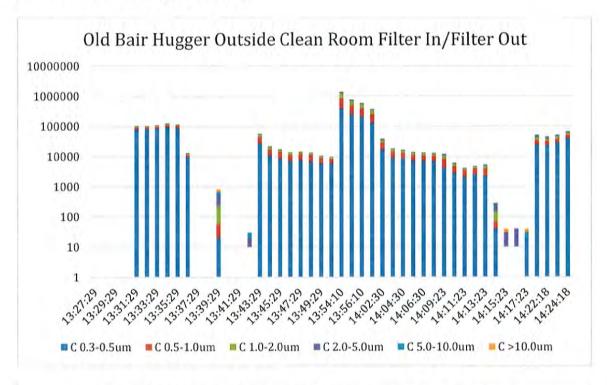
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also completed with both a used Bair Hugger Model 750 and new Bair Hugger model 775. Again, these evaluations showed particles coming out of both the new and the used Bair Hugger devices.



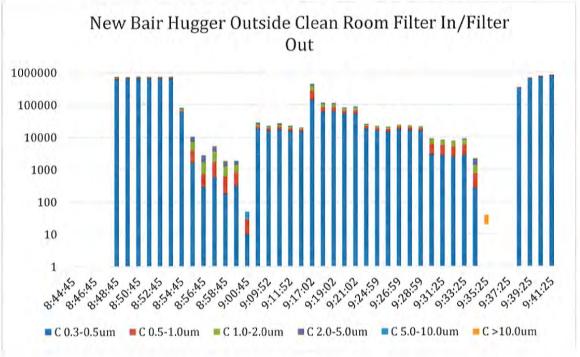
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2. Tests on the Bair Hugger Machine with Blankets

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A third evaluation was carried out in a HEPA filtered (99.97% for .3 μ m sized particles) a simulated operating room using a laser optical particle counters that recorded differential particle sizes ranging from .02 μ up to greater than 10 μ in size. The particle counter isokinetic probe was mounted inside a container where the Bair Hugger air supply hose discharged with the Bair Hugger blower placed on the floor of the operating room.

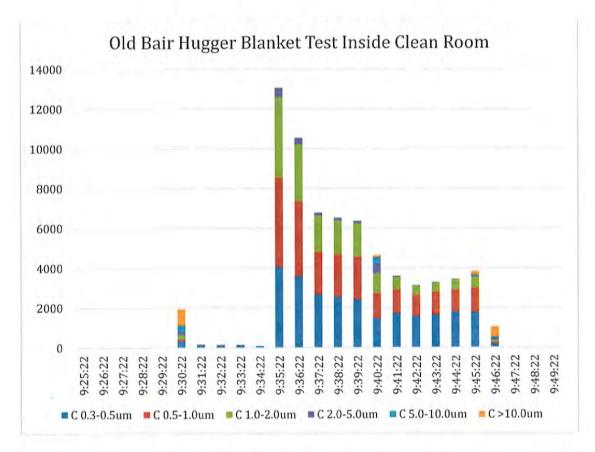




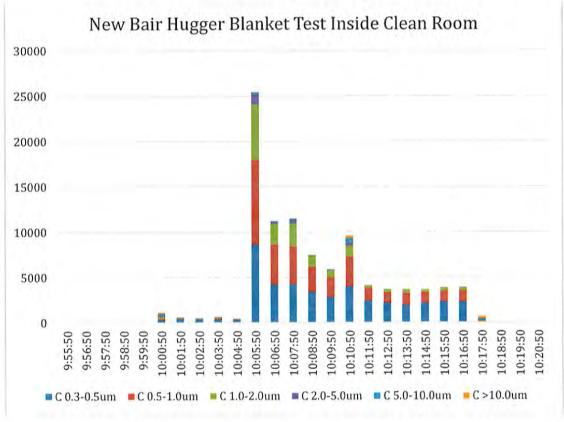
The Bair Hugger was evaluated using normal operating modes (43°C, and blanket paper side down) to establish the initial discharge of air (particles) from the end of the air supply hose. In addition, a new upper body blanket (Model 52200) was attached to the air supply hose inside the box and particles that were released from the blanket were measured.



The evaluation of the air discharge was carried out through each operational mode and particle counts were collected at one minute continuous intervals to validate air quality content of the Bair Hugger and blanket. Again, this experiment confirmed particles coming out of both the new and used Bair Hugger machines when connected to new disposable upper body Bair Hugger blankets.



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A complete copy of the log graphs reflecting data obtained from each of these evaluations is attached at Exhibit B.

IV. CONCLUSIONS/SUMMARY OF OPINIONS

The evaluations showed clearly the Bair Huggers - through all operational modes - demonstrated increased production of particles from internal and/or external sources. This was true for both new and "used" machines, both with the filter in place and without the filter in place, as well as when connected to the disposable upper body blanket. These findings are consistent with both published literature and internal Arizant and 3M Company documents. It is my professional opinion that the Bair Hugger causes an increase in the number of particles in the operating room, and in particular, in close proximity to the surgical site. I reserve the right to amend the opinions in this report if further information becomes available to me.

MICHAEL W. BUCK

HEALTH CARE AND ENVIRONMENTAL

CONSULTING, INC.

13065 Isanti Street NE

Blaine, Minnesota 55449-4943

EXHIBIT A – CIRRICULUM VITAE

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MICHAEL W. BUCK

13065 Isanti Street NE Blaine, Minnesota 55449-4943 763/355-7612

Curriculum Vitae

Areas of Interest - Hospital Environment Consulting.

EDUCATION:

University of Minnesota

Minneapolis, Minnesota

School of Public Health - completed most course work (39 graduate credits) for a master's of Public Health in Industrial Hygiene.

Minot State University

Minot, North Dakota

Bachelor of Arts, Biology, February 27, 1989

Concentrations: Physical Science, Chemistry, Economics, Psychology

Experience:

President - Mike Buck, Health Care and Environmental Consulting,

Incorporated 2007

- Provide national consulting for hospital certification of critical care environments (i.e. BMT, ICU, NICU, and OR) ventilation systems and air and surface sampling
- Provide Training to HVAC mechanics and building managers on water infiltration remediation techniques and construction related activities relating to infection control procedures
- Provide industrial hygiene consulting to real estate property management companies

Environmental Health and Safety Compliance Specialist 2000 - Present

Environmental Health and Safety - U of MN

Minneapolis, Minnesota

- Conduct indoor air quality investigations and coordinate remediation activities
- Coordinate sample collection of University Hospital's anesthetic gas employee exposure program
- Manage Department's Micro Lab including sample tracking and analysis
- Repair and maintain Department's air quality sampling equipment
- Audit Facilities Management Hazardous Material Program and outside contractor abatement projects and address concerns
- · Review construction plans and provide comments on IAQ concerns and hazardous materials
- Participate in the University's After Hours Emergency Response (AHERPS) program requiring fundamental knowledge of hazardous, radioactive and biological spill response techniques

Principal Safety Technician

1991 - 2000

Environmental Health and Safety - U of MN Minneapolis, Minnesota

- · Conduct building hazard assessments and communicate results
- Supervise asbestos abatement projects including contractor coordination and building communication; including project tracing and invoicing

Industrial Hygiene Technician

1989 - 1991

Delta Environmental Consultants

St. Paul, Minnesota

· Project manager for asbestos site surveys and abatement projects

IAQ Investigations:

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2017 - Woman's Hospital OR's Baton Rouge, Louisiana

2016-2017 Plaintiffs Retained Consultant, MDL #2666: In re: Bair Hugger Products Liability Litigation (Minneapolis, MN)

2017 - Ann and Robert H. Lurie Children's Hospital of Chicago, Northbrook, IL

2016 - Shriners Hospital for Children, First/Second Floors OSHA Investigation, Minneapolis,

2016 - University of Michigan Medical Center, Ann Arbor, MI

2016 - AI Nemours DuPont Hospital for Children, Wilmington, DE

2016 - Shriners Hospital for Children Kitchen flood, Minneapolis, MN

2016 - Shriners Hospital for Children First Floor Renovation, Minneapolis, MN

2016 - UPMC - University of Pittsburgh Medical Center

2015 - UPMC - University of Pittsburgh Medical Center

2015 - Shriners Hospital for Children, Minneapolis, MN

2015 - HCMC - Hennepin County Medical Center Burn Unit

2015 - Children's National BMT, Washington DC

2014 - HCMC - Hennepin County Medical Center Risk Assessment for Demolition

2013 - South Nassau Community Hospital, Oceanside NY

2013-2014 Stanford Medical Center Hospital Construction Annual Consultant, Palo Alto

2013 - Stanford Medical Center Hospital Construction, Palo Alto California

2013 - Riverwood Healthcare Center OR's

2013 - Regina Medical Center OR's

2013 - Regency Hospital Golden Valley

2013 - Fairview Southdale Medical Center

2012 - Regina Medical Center Grace Unit

2012 - Regina Medical Center Material Management Room

2012-2015 Oppenheimer Law Firm Project Consultant

2011 - Riverwood Healthcare Center Addition

2011 - Riverwood Healthcare Center MRI

2010 - Avera Regional Medical Center OR's

2010 - Avera Regional Medical Center OR's, Recovery, and Endoscopy

2010 - Southdale Medical Center

2009 - St. Joes Hospital, St. Paul, MN

2009 - Avera Regional Medical Center OR's

2008 - Jewish Medical Center, Louisville Kentucky

2007 - Avera Regional Medical Center OR's

2007 - Children's National BMT, Washington DC

2007 - Rush Memorial Chicago

2007 - Modesto Hospital Trials Ventilation Study with Mazetti and EH Price

2006 - Northeast Georgia Medical Center Women's and Children's Pavilion

2006 - Northeast Georgia Medical Center ICU

2006 - Northeast Georgia Medical Center Outpatient Services Building

2006 - Northeast Georgia Medical Center School of Nursing

2006 - Natchez Regional Hospital

2004 - Pitt County Memorial Hospital Emergency Department

2004-2006 - Pitt County Memorial Hospital NICU Assessment and Remediation Consultant

2004-2006 - Pitt County Memorial Hospital NICU Assessment and Remediation

2003 - MD Anderson Cancer Center Research Facility Construction

2003 - Pitt Count Memorial Hospital

2003 - Pitt Count Memorial Hospital Community Services Building

2003 - Pitt Count Memorial Hospital Emergency Department

Publications

- APIC 2015 Infection Prevention Manual for Construction and Renovation Author Chapter 5:
 Air Monitoring for Quality Evaluation in Healthcare
- Published 2010: Displacement Ventilation as a Viable Air Solution for Hospital Patient Rooms

Conference Presentations

2016 APIC Pittsburg, Water Damage Management in Healthcare Facilities

2016 APIC Minnesota, Water Damage Management in Healthcare Facilities

2014 Construction Management in Healthcare Facilities, Winnipeg, Manitoba Canada Webcast to Provincial Healthcare Board

2010 Healthcare Occupational and Environmental Safety Workshop, Evaluation Methods and Exposure Monitoring of Anesthetic Gases

2008 ERTK, University of Minnesota Duluth

2005 OSHA Respiratory Protection Program Lakes and Plains Regional Training Center

2004 MultiData Corporation: Mold investigations

2004 Construction Management in Healthcare Facilities, University of Minnesota

2003 Construction Management in Healthcare Facilities, University of Minnesota

2003 Mold Management in Healthcare Facilities, University of Minnesota

2003 Mold Management in Healthcare Facilities, University of Minnesota

2003 Mold Investigations, Omaha Regional Conference of Air Conditioning Heating and Refrigeration Professionals

TRAINING - Current Certifications: Asbestos Contractor Supervisor Training Recognition of Indoor Air Quality Issues Introduction to Food and Air-Borne Fungi

NIOSH 582 - Asbestos Air Analysis Building Inspector Hazardous Materials Asbestos Abatement Site Supervisor

Applied Thermographer using Infrared Technology

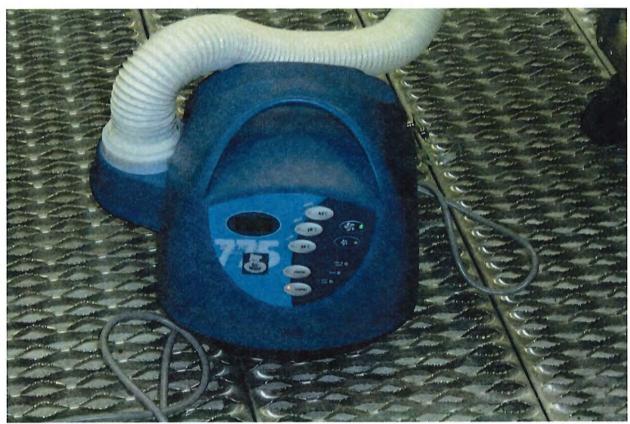
TRAINING - Past Certifications: OSHA 501 Certified Trainer Asbestos Project Designer Lead Risk Assessor Lead Inspector

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EXHIBIT B – GRAPHS AND PHOTOS OF EXPERIMENTS

Bair Hugger 1st Set of Tests



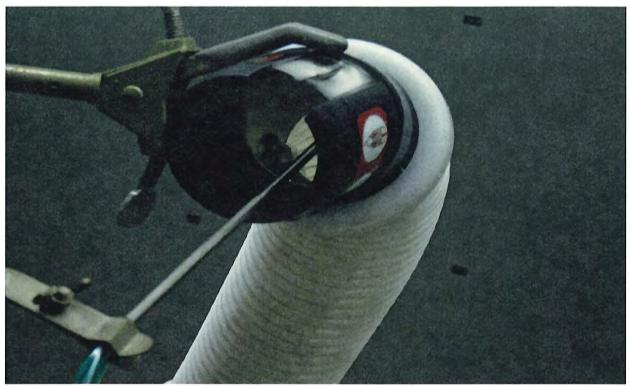
Picture #1 – Bair Hugger in Clean room

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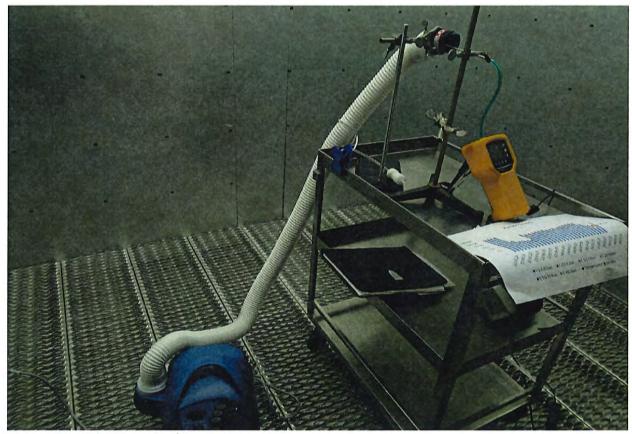


Picture #2 – Bair Hugger in Clean Room with particle counter in center of hose

Bair Hugger 1st Set of Tests



Picture #3 – Bair Hugger in Clean Room particle counter probe sampling Bair Hugger air output



Picture #4 – Bair Hugger in Clean Room

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0

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Bair Hugger 2nd Set of Tests



Picture #1 - Bair Hugger in Clean Room with blanket attached to supply air output hose in container

0



Picture #2 – Bair Hugger in Clean Room with blanket attached to supply air output hose in container

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Bair Hugger 2nd Set of Tests

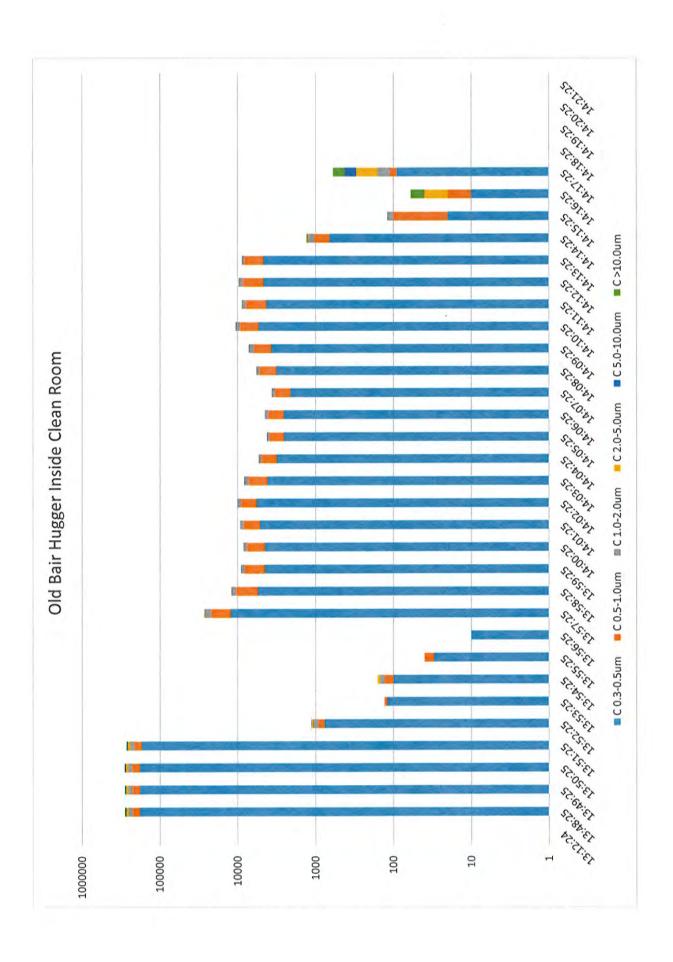


Picture #3 – Bair Hugger in Clean Room particle counter

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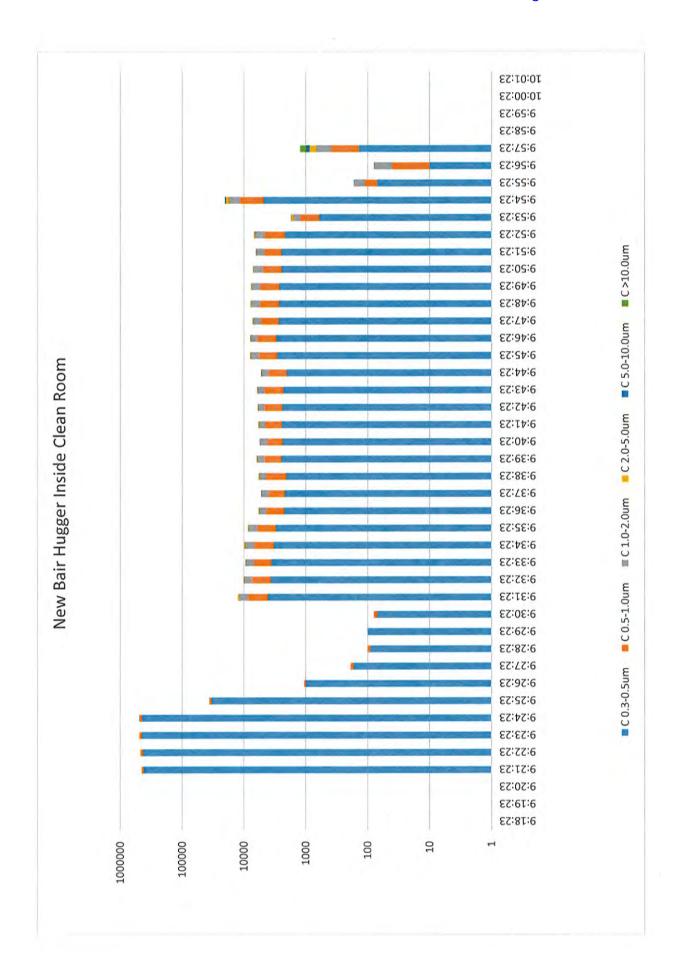
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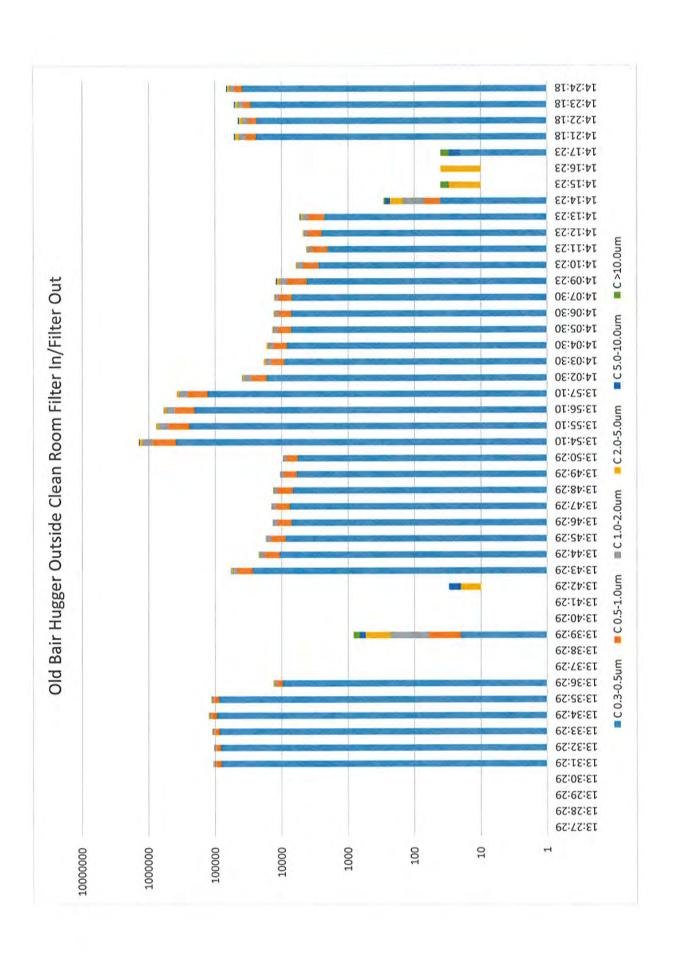


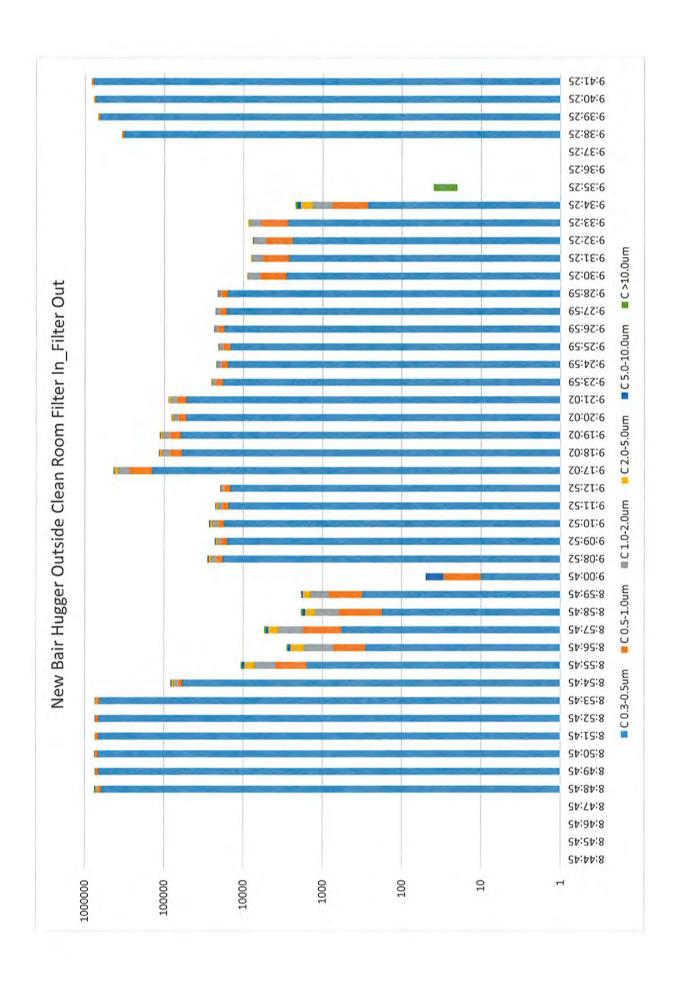
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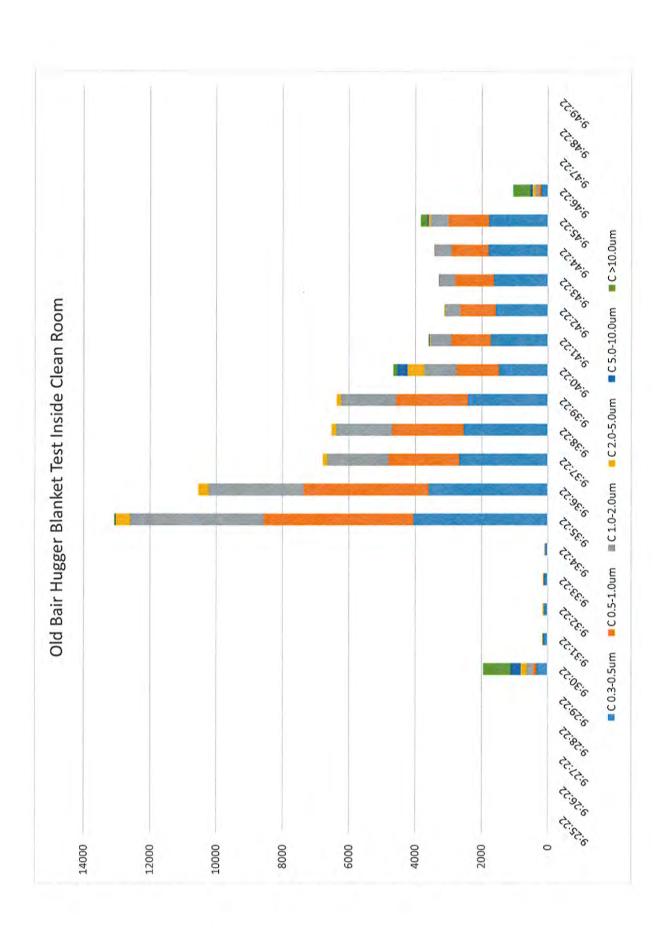


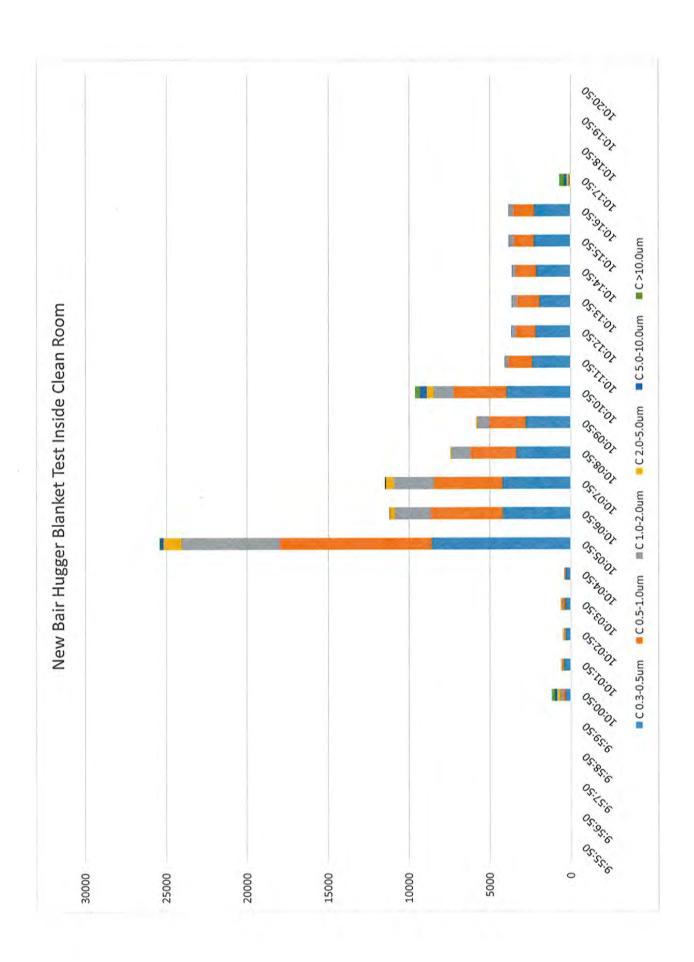
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EXHIBIT C – REFERENCES & DOCUMENTS CONSIDERED

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3MBH00001579	3MBH00024728	3MBH00105804
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3MBH00001582	3MBH00025739	3MBH00105839 - 40
3MBH00001583 - 87	3MBH00030403	3MBH00105841 - 42
3MBH00002412 - 13	3MBH00030796	3MBH00105843
3MBH00002430	3MBH00030875 - 907	3MBH00105845 - 47
3MBH00002433	3MBH00031134 - 58	3MBH00106405 - 06
3MBH00002508	3MBH00031184 - 86	3MBH00107694 - 96
3MBH00002513 - 17	3MBH00031212	3MBH00107719 - 20
3MBH00002556 - 68	3MBH00031537 - 55	3MBH00107862 - 72
3MBH00002619 - 20	3MBH00039330 - 35	3MBH00107972
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3MBH00127752 - 128189

3MBH00128190 - 129010

3MBH00497102 - 497359

3MBH00498164 - 498341

Augustine_00125751 - 12964

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EXHIBIT DX38

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS



DUKE INFECTION CONTROL OUTREACH NETWORK (DICON)

Infection Prevention News

Volume 10, Number 11, November 2015

HotDogs, Bair Huggers, and Lawsuits, Oh My! A brief review of the controversy surrounding perioperative warming methods.

Maintenance of Perioperative Normothermia: Background and Rationale

A 2-degree Celsius decrease in body temperature in patients undergoing general anesthesia can triple the rate of a postoperative wound infection. The benefits of maintaining normothermia in surgical patients have been extensively studied. These benefits include: 1) reduction of risk of surgical site infection, 2) better coagulation, and 3) faster discharge from the post-anaesthesia care unit. (1, 2)

Maintenance of normothermia is now a standard of care and a key component of the Surgical Care Improvement Project (SCIP). Also, adherence to normothermia protocol is a current requirement for receipt of full reimbursement from CMS. (3)

Most operating rooms, including ours, rely on forced air warming (FAW) devices, such as the Bair Hugger, to ensure normothermia during surgery. FAW warming devices circulate warmed air in a hose connected to a disposable and inflatable blanket. All clinical trials that documented the benefit of maintaining normothermia during surgery have used FAW devices. (1,2)

Resistive Polymer Warming (RPW), FAW's competition:

RPW devices (HotDog) warm patients by passing an electric current through a resistive polymer which in turn is encased in a reusable blanket. In contrast to FAW devices, RPW devices require direct contact with a patient's skin. The warming capacity of RPW devices was compared to that of FAW devices in a 2011 study by Kimberger et al. This study showed that RPW warmed anaesthetized ENT patients at a slower rate. (4)

Current controversies:

Most operating rooms typically utilize "ultraclean air ventilation" during joint replacement procedures. "Ultraclean air ventilation" relies on constant and unidirectional filtered air flow, known as laminar flow, to protect the surgical site from airborne contamination.

A few investigators have speculated that use of FAW devices disrupts laminar flow thus potentially increasing the risk of contamination of the operative site. (5-7) Most studies that reached these conclusions were funded by the manufacturer of a single RPW device. This same company currently

sponsors "informative websites" that emphasize their claims of an increased risk of developing a surgical site infection due to the use of FAW warming devices while simultaneously promoting their alternative RPW product.

A single study done by McGovern et al is the primary source and most commonly quoted evidence for the claim that FAW warming devices are unsafe. (8) These authors evaluated ventilation airflow patterns using a machine that emitted "neutrally buoyant detergent bubbles" during a simulated hip arthroplasty and a lumbar spinal surgical procedure done on mannequins in order determine if laminar airflow was differentially and adversely disrupted by the use of a FAW warming device compared to the use of a RPW warming device. Photographs were used to provide data on "bubble counts" over the operative site during these mock surgical procedures. Bubble counts on operative site over mannequins were higher when FAW devices were used. No actual microbiologic data was collected during this portion of the experiment. (8)

McGovern et al also examined rates of surgical site infection (SSI) after use of either a FAW or RPW warming device in a total of 1,437 patients undergoing knee and hip replacements over a 2.5-year period. They concluded that the risk developing a SSI was higher in patients undergoing arthroplasty procedures when FAW warming devices were used than when RPW warming devices were used (OR 3.8, 95% CI (1.2-12.5), p=0.024). Curiously the risk of developing a SSI was remarkably higher in patients undergoing hip replacement procedures with the use of FAW warming devices than in patients undergoing knee replacements warmed with the same FAW devices (OR 4.1, 95% CI (1.9-8.6), p <0.001). (8)

We and others (3) believe that the preceding widely quoted study by McGovern et al has significant limitations: 1) infection control practices and perioperative antibiotics were not standardized in the two study groups, and 2) the authors did not adjust their outcomes for age or other important patient-related comorbidities. Moreover, the authors failed to discuss what these important details: 1) no mention was made of whether the FAW devices used in this study had proper maintenance including appropriately timed changing of filters in their tubing (see table); 2) they did not provide sufficient supporting data to document that the use of "neutrally buoyant detergent bubbles" are a valid proxy for bacterial contamination, and 3) they did not discuss or explain why patients undergoing hip arthroplasty procedures had such high rates of SSI in their study.

Our take:

The body of evidence describing the link between FAW and increased operative site infections is weak. To the best of our knowledge, no adequately powered, properly controlled, statistically significant, reproducible study has been published that demonstrates an increased risk of SSI due to the use of FAW warming devices. We do not believe that experimental studies using machines that emit bubbles in mock surgical procedures is a proven or standardized method to assess the risk of operative site contamination. Finally, we believe it is important and notable that no studies performed by independent investigators have been published that confirm the findings of the study by McGovern et al. Until such data are published, we believe that it is reasonable and appropriate to continue the use of FAW warming devices in patients. Indeed, our data and that collected by the NHSN suggest that

approximately 99% of patients undergoing joint replacement procedures do not develop a SSI despite the fact that FAW warming devices continue to be widely and appropriately used.

Conclusions:

- We continue to believe that it is reasonable and appropriate to use FAW warming devices to maintain normothermia as these devices are the only devices proven to decrease the risk of developing a post-operative infection.
- FAW warming devices have a >20-year track record of safety in >200 million surgical patients.
- FAW devices should be regularly undergo maintenance as outlined by manufacturer's guidelines, see attached table for recommendations.

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Warming Unit Information and Table

"The repair, calibration, and servicing of the warming unit requires the skill of a qualified medical equipment service technician who is familiar with good practice for medical device repair" —3M Bair Hugger Manual (http://multimedia.3m.com/mws/media/7983990/service-manual-english.pdf)

Refer to your model manual for exact specifications. The table below is a general guide, and should not replace model specific guidelines.

TABLE I

Proper Maintenance and Use of Forced Air Warmers

Recommendations

- 1. The filter should be changed every 6 months or 500 hours. A counter is available on some devices (e.g., Bair Hugger 700 series) to indicate the total hours of use.
- 2. Calibration testing should occur every six months by biomedical engineering staff at the user's institution. The manufacturer should check or replace devices that fail calibration testing.
- 3. Do not warm patients with the warming unit's hose alone, as severe thermal injury may occur. Always connect the hose to a new, manufacturer-approved warming gown for each patient.
- 4. Do not continue warming if the red over-temperature indicator light illuminates or an audible alarm sounds, as thermal injury may result. Turn the warming unit off immediately and check the patient's skin.
- 5. Do not use a forced air warming device over transdermal medications; increased drug delivery and patient death or injury may result.
- 6. Do not allow the patient to lie on the warming unit hose or allow the hose to contact the patient's skin during patient warming.
- 7. Equipment is not suitable for use in the presence of a flammable anesthetic mixture (e.g., containing air, oxygen, or nitrous oxide).
- 8. Do not place the non-perforated side of the blanket on the patient. Thermal injury may result. Always place the perforated side (the side with small holes) toward the patient.

Recommendations

- 9. The warming device should be disconnected from the power source before cleaning. Between patients, the outside of the hose should be cleaned with a damp, soft cloth and a mild detergent or antimicrobial spray and then dried with a separate cloth.
- 10. If a fault occurs in the unit, unplug the temperature management unit and wait for five minutes. Reconnect the temperature management unit to a grounded power source. The unit will perform the normal power-on-reset sequence and then enter the standby mode. If the unit does not return to normal operation, contact a service technician.
- 11. Temperature and calibration testing should be performed every 6 months or 500 hours of use.

Taken from Sikka, RS *J Bone Joint Surg Am*, 2014 Dec 17; 96 (24): e200 . http://dx.doi.org/10.2106/JBJS.N.00054

EXHIBIT DX39

TO DECLARATION OF PETER J. GOSS IN
SUPPORT OF DEFENDANTS' MOTION TO
EXCLUDE PLAINTIFFS' ENGINEERING
EXPERTS

	Page 1
1	KOENIGSHOFER
2	UNITED STATES DISTRICT COURT
3	DISTRICT OF MINNESOTA
4	
5	In Re:
6	Bair Hugger Forced Air Warming
7	Products Liability Litigation
8	This Document Relates To:
9	All Actions MDL No. 15-2666 (JNE/FLN)
10	
11	VIDEOTAPED DEPOSITION DANIEL KOENIGSHOFER, P.E.
12	Chapel Hill, North Carolina
13	June 13, 2017
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19	
20	
21	
22	
23	
24	Randi J. Garcia, RPR
25	Job no. 124784

Page 54 Page 55 1 **KOENIGSHOFER KOENIGSHOFER** 2 2 Q. And it says, "But most agree about associated infections result from endogenous 3 3 90 percent of HAIs are transmitted by direct sources? 4 contact with about 10 percent resulting from 4 MS. ZIMMERMAN: Object to the form of 5 5 airborne transmission." the question. Foundation. And misstates 6 Do you agree with that statement? the prior testimony. 7 7 A. Yes. I've seen publications anywhere THE WITNESS: I couldn't answer that 8 8 from five to 20, but those are about 10. question anyway. I don't know the answer. 9 Q. Going back to the question I asked BY MR. GOSS: 10 10 earlier about endogenous and exogenous sources Q. So are you saying there's a 11 11 difference between infections transmitted by of surgical site infections, would the same 12 percentage apply to infections from exogenous 12 direct contact and infections from endogenous 13 13 sources versus endogenous, meaning -- that's a sources? 14 14 bad question. MS. ZIMMERMAN: Objection to form. 15 A. Yes. 15 BY MR. GOSS: 16 16 Q. Or can you answer that? Q. Would you say that approximately --17 MS. ZIMMERMAN: I'm going to 17 A. I can't answer that question. 18 18 Q. Would you need microbiological object --19 MR. GOSS: Go ahead. 19 expertise to answer that question? 2.0 MS. ZIMMERMAN: I'll let you finish. 20 MS. ZIMMERMAN: Object to form. 21 21 Then I'll jump in and then you can jump THE WITNESS: I would, yes. 22 22 in. BY MR. GOSS: 23 BY MR. GOSS: 23 Q. And fair to say you're not a 24 2.4 Q. Would you say that approximately microbiologist? 25 90 percent of hospital-acquired infections or 25 A. Correct. Page 56 Page 57 1 **KOENIGSHOFER** 1 KOENIGSHOFER 2 Q. Any other publications on Exhibit 6 2 from surgery; is that right? 3 3 that relate to surgical site infections? A. Yes. 4 4 A. No. Q. What type of surgery was it? 5 5 O. Have you written any articles on the A. Open-heart. 6 potential for medical equipment to interfere 6 Q. What type of infection? 7 7 with operating room airflow? A. Fungal infection on the outside of 8 8 A. No. the heart. 9 9 Q. Have you written any articles Q. And what field work did you do in 10 specific to patient warming devices? 10 that case? 11 11 A. No. A. I looked inside the air handler that 12 12 Q. Let's go back to your resume, please. served the space, and I looked in the ductwork 13 13 Exhibit A to the report. Let's see. The that served the particular OR where the 14 fourth paragraph talks about your hands-on 14 infection occurred. And then I looked inside 15 15 engineering experience. And the last sentence the OR and inside the laminar diffuser. 16 16 says, "He has personally designed every Q. And when you say you looked inside, 17 17 discipline in healthcare engineering, including were you taking samples of anything? 18 med gas, fire alarm, electrical, mechanical, 18 A. Well, I was -- I was -- I didn't do 19 19 sprinklers, HVAC, emergency power, et cetera." any instrumentation at all other than 2.0 20 And my question is: Have you ever temperature and humidity, well, and a Kleenex designed a medical device? 21 21 for pressurization. But when a piece of black 22 A. No. 22 insulation fell out of the diffuser when I 23 23 Q. The paragraph right above that opened it, I guess you could say that I took a 24 24 mentions your previous role as an expert sample. 25 25 witness. And the case involved an infection Q. Okay. So did you send the insulation

Page 66 Page 67 **KOENIGSHOFER KOENIGSHOFER** 2 2 only testify for plaintiffs or were you open to week. 3 3 testifying for defendants? Q. Are you still an employee or do you 4 A. B. 4 have an independent contract relationship with 5 5 them? How would you characterize it? O. So both? 6 6 A. Yes. A. It's complicated. Basically, I can't 7 7 really answer that question, not because I Q. Since you put this listing up, have 8 8 you gotten any calls, any potential referrals? won't, but I can't. I do get -- I can work 9 A. I got a call from a guy whose air however many hours I want and I get paid 10 10 conditioner burned up in his house. And a call hourly. And I get a paycheck from them, which -- from which they do withholding. But I 11 from a lady who had, I don't know, mold in her 11 12 crawl space or something. And I turned them 12 don't get any benefits. 13 Q. Do your expert fees for your work on 13 both down. 14 14 this case go to Dewberry? Q. Have you been approached ever by any 15 A. No. 15 manufacturers of HVAC equipment to serve as an 16 16 Q. And did you need to ask Dewberry for expert witness in their cases? 17 permission to participate as an expert in this 17 A. No. 18 18 case? Q. Have you ever had any conversations 19 19 with any manufacturers of HVAC equipment about A. No. I mean, you know, again, the 20 litigation that they were involved in? That 20 agreement is I'm not going to do anything that, 21 basically that Dewberry has anything to do 21 you can recall. 22 22 with. A. No. 23 23 Q. So are you currently employed by Q. Have you talked to anyone at Dewberry 24 24 about the fact that you were retained as an Dewberry? 25 expert witness in this case? 25 A. I work for them about 20 hours a Page 68 Page 69 1 KOENIGSHOFER 1 **KOENIGSHOFER** 2 2 A. Well, as you know, I didn't get a 3 whole lot of warning about it. So I carefully Q. Who have you spoken to about that? 4 4 A. Shepherd Hockaday. reviewed my report. Then I reviewed the 5 O. And who is that? 5 reports that I cited in my report and gathered 6 6 a few others, but I didn't really get around to A. He's sort of my boss. 7 7 Q. Did you talk to Mr. Hockaday about reading much of anything else. 8 8 the deposition today? O. So you reviewed your report. Did you 9 9 A. Probably not. Probably not. have occasion to revisit any of your opinions? 10 10 Q. What was the nature of your A. No. I mean, I marked it up a little 11 11 conversation with Mr. Hockaday about your bit for typos and things I found in it. 12 participation as an expert in this case? 12 Q. Is there anything in your report that 13 13 you felt you needed to amend or modify? A. It was just casual conversation. 14 14 A. Well, only one thing, but at some What are you up to these days? What are you 15 15 doing with all your time besides playing golf? point toward the end of my report, I said that 16 16 Q. Did you talk to Mr. Hockaday about the Bair Hugger might put out 50 to 100 CFM. 17 17 your opinions in this case? Honestly, I don't know where I got the 100, 18 18 A. No. but... 19 19 Q. We covered Mr. Hockaday. Q. Okay. 2.0 2.0 Have you talked to anyone outside A. It should have read "about 50." 21 2.1 from counsel at this table in preparation for Q. So this is on page 23 of the report, 22 your deposition today? 22 right at the top of the page? 23 23 A. That's correct. That's correct. A. No. 24 24 Q. You say, "50 to 100 CFM are blown Q. Can you tell me what you did to 25 25 prepare for the deposition today? from the blanket into or near the sterile

	Page 70		Page 71
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1	KOENIGSHOFER	1	KOENIGSHOFER
2	field." And you're saying that that should	2	that airflow is?
3	read "about 50 CFM"; is that right?	3	A. I think some of them are in the range
4	A. Yes. Yes.	4	of 35, 30 CFM, something like that.
5	Q. And what is the 50 based on?	5	Q. So if the 505 were about 30 CFM,
6	A. Well, one of the I'm not a Bair	6	would you have any reason to disagree with
7	Hugger expert. One of them puts out about 48	7	that?
8	CFM. I can't remember which one. I couldn't	8	A. I would have to look it up.
9	cite the model for you.	9	Honestly, I don't remember which is which.
10	Q. So if I told you that the	10	Q. All right. Anything else in your
11	specifications for the 750/775 say it will put	11	report after reviewing it that you felt you
12	out up to 48 CFMs, does that sound right to	12	needed to amend or modify?
13	you?	13	A. No. Again, other than just typos.
14	A. Yes.	14	Q. Okay. In preparation for your
15	Q. Are you familiar with another model	15	deposition today, did you review any documents
16	of Bair Hugger that's at issue in this case?	16	from 3M or Arizant?
17	A. You know, only in a very general way.	17	A. So you're saying in the last two or
18	I realize there's a 505 and 550 and a 700 or	18	three weeks since I've known I was going to be
19	whatever. I did not make an effort to memorize	19	deposed?
20 21	the nuances of the different models.	20	Q. Yeah. Let's start with that.
	Q. Did you have an understanding that	21	A. No.
22 23	the airflow rate of other models might be	22	Q. Before that, have you reviewed
24	different from the 750/775?	23	documents from 3M or Arizant?
25	A. Yes, I know that.	24	A. Yes.
25	Q. Do you do you know roughly what	25	Q. Were you provided a copy of the
	Page 72		Page 73
1	Page 72	1	Page 73
1 2	KOENIGSHOFER	1 2	KOENIGSHOFER
2	KOENIGSHOFER protective order in this case that designates	2	KOENIGSHOFER A. No.
	KOENIGSHOFER protective order in this case that designates certain documents as confidential?		KOENIGSHOFER A. No. Q. Did I get that right?
2	KOENIGSHOFER protective order in this case that designates certain documents as confidential? A. Yes.	2	KOENIGSHOFER A. No. Q. Did I get that right? MR. ASSAAD: Close enough.
2 3 4	KOENIGSHOFER protective order in this case that designates certain documents as confidential? A. Yes. Q. And have you signed an acknowledgment	2 3 4	KOENIGSHOFER A. No. Q. Did I get that right? MR. ASSAAD: Close enough. MR. GOSS: Is it David?
2 3 4 5	KOENIGSHOFER protective order in this case that designates certain documents as confidential? A. Yes. Q. And have you signed an acknowledgment to be bound by it?	2 3 4 5	KOENIGSHOFER A. No. Q. Did I get that right? MR. ASSAAD: Close enough. MR. GOSS: Is it David? MR. ASSAAD: David, yes.
2 3 4 5 6 7	KOENIGSHOFER protective order in this case that designates certain documents as confidential? A. Yes. Q. And have you signed an acknowledgment to be bound by it? A. Yes.	2 3 4 5 6 7	KOENIGSHOFER A. No. Q. Did I get that right? MR. ASSAAD: Close enough. MR. GOSS: Is it David? MR. ASSAAD: David, yes. MR. GOSS: It is David. Okay.
2 3 4 5 6	KOENIGSHOFER protective order in this case that designates certain documents as confidential? A. Yes. Q. And have you signed an acknowledgment to be bound by it? A. Yes. MS. ZIMMERMAN: It's in the binder.	2 3 4 5 6	KOENIGSHOFER A. No. Q. Did I get that right? MR. ASSAAD: Close enough. MR. GOSS: Is it David? MR. ASSAAD: David, yes. MR. GOSS: It is David. Okay. THE WITNESS: Never heard the name.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	KOENIGSHOFER protective order in this case that designates certain documents as confidential? A. Yes. Q. And have you signed an acknowledgment to be bound by it? A. Yes. MS. ZIMMERMAN: It's in the binder. MR. GOSS: Okay. Thanks. BY MR. GOSS: Q. In preparing for your deposition today, have you reviewed any reports from other plaintiff's experts? A. Yes. Q. Which ones did you review? A. Keen, K-E-E-N, Koehn, K-O-E-H-N, I believe. Q. I'm going start just by asking about plaintiff's experts. Experts on the plaintiff's side. A. Oh, Elghobashi. Q. Okay.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	KOENIGSHOFER A. No. Q. Did I get that right? MR. ASSAAD: Close enough. MR. GOSS: Is it David? MR. ASSAAD: David, yes. MR. GOSS: It is David. Okay. THE WITNESS: Never heard the name. BY MR. GOSS: Q. Did you review a report by Michael Buck? A. No. Q. Did you review a report by William Jarvis? A. No. Q. So you started out mentioning that you reviewed reports by Keen and Kuehn, which he actually pronounces it Keen too, so they're both Keens. And I'll just tell you for a shorthand, the way I keep it straight is there's an American Kuehn and a Canadian Keen. A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	KOENIGSHOFER protective order in this case that designates certain documents as confidential? A. Yes. Q. And have you signed an acknowledgment to be bound by it? A. Yes. MS. ZIMMERMAN: It's in the binder. MR. GOSS: Okay. Thanks. BY MR. GOSS: Q. In preparing for your deposition today, have you reviewed any reports from other plaintiff's experts? A. Yes. Q. Which ones did you review? A. Keen, K-E-E-N, Koehn, K-O-E-H-N, I believe. Q. I'm going start just by asking about plaintiff's experts. Experts on the plaintiff's side. A. Oh, Elghobashi. Q. Okay. A. I think that's it.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	KOENIGSHOFER A. No. Q. Did I get that right? MR. ASSAAD: Close enough. MR. GOSS: Is it David? MR. ASSAAD: David, yes. MR. GOSS: It is David. Okay. THE WITNESS: Never heard the name. BY MR. GOSS: Q. Did you review a report by Michael Buck? A. No. Q. Did you review a report by William Jarvis? A. No. Q. So you started out mentioning that you reviewed reports by Keen and Kuehn, which he actually pronounces it Keen too, so they're both Keens. And I'll just tell you for a shorthand, the way I keep it straight is there's an American Kuehn and a Canadian Keen. A. Yes. Q. All right. Do you know either of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	KOENIGSHOFER protective order in this case that designates certain documents as confidential? A. Yes. Q. And have you signed an acknowledgment to be bound by it? A. Yes. MS. ZIMMERMAN: It's in the binder. MR. GOSS: Okay. Thanks. BY MR. GOSS: Q. In preparing for your deposition today, have you reviewed any reports from other plaintiff's experts? A. Yes. Q. Which ones did you review? A. Keen, K-E-E-N, Koehn, K-O-E-H-N, I believe. Q. I'm going start just by asking about plaintiff's experts. Experts on the plaintiff's side. A. Oh, Elghobashi. Q. Okay.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	KOENIGSHOFER A. No. Q. Did I get that right? MR. ASSAAD: Close enough. MR. GOSS: Is it David? MR. ASSAAD: David, yes. MR. GOSS: It is David. Okay. THE WITNESS: Never heard the name. BY MR. GOSS: Q. Did you review a report by Michael Buck? A. No. Q. Did you review a report by William Jarvis? A. No. Q. So you started out mentioning that you reviewed reports by Keen and Kuehn, which he actually pronounces it Keen too, so they're both Keens. And I'll just tell you for a shorthand, the way I keep it straight is there's an American Kuehn and a Canadian Keen. A. Yes.

	Page 78		Page 79
1	KOENIGSHOFER	1	KOENIGSHOFER
2	deposition.	2	view of a Bair Hugger on one of their
3	Q. Van Duren?	3	maintenance manuals that's available online.
4	A. Van Duren.	4	Q. Okay. And why did you do that?
5	Q. Was that in the last two or three	5	A. See how it's built.
6	weeks?	6	Q. Was that something you did in the
7		7	last couple weeks to prepare for today?
8	A. No. I guess I'd have to look at the book again. I read some other expert's stuff	8	A. No.
9	· · · · · · · · · · · · · · · · · · ·	9	
10	and I can't remember who. Not expert,	10	Q. Was there anything about that exploded view of the Bair Hugger that
11	deposition.	11	
12	Q. Some other depositions? And I'm	12	contributed to your opinions in this case? A. Yes. Well, I mean, I looked
13	really just asking for what you can remember,	13	
14	what stands out in your mind as significant	14	carefully at how the filtration works.
15	that you reviewed to prepare for today. We've	15	Q. So from the exploded view of the Bair
16	covered the Elghobashi expert report from the	16	Hugger, you could tell how the filtration works in the unit?
17	plaintiffs, the four expert reports from the	17	
18	defense. Any other documents that you spent	18	A. Well, how it's installed, yes.
19	particular gave particular focus or	19	Q. Okay. Obviously, you met with
20	attention to prepare for today?	20	counsel to prepare for the deposition today; correct?
21	MS. ZIMMERMAN: In addition to his	21	A. Yes.
22	report.	22	
23	BY MR. GOSS:	23	Q. And I'm not going to ask you about specific documents you reviewed with them. I
24	Q. In addition to your report. That's	24	just want to know how many meetings did you
25	right.	25	have with them to prepare for today?
25	A. Well, I mean, I looked at an exploded		have with them to prepare for today:
	Page 80		Page 81
1	KOENIGSHOFER	1	KOENIGSHOFER
2	A. One.	2	Q. Do you have expertise in heat
3	Q. Was that	3	transfer?
4	A. Yesterday.	4	A. I understand heat transfer. I'm not
5	Q. So the meeting you had in	5	6 61 6
6	Minneapolis, was that more to do with your		a professor of heat transfer.
-	Willieapons, was that more to do with your	6	a professor of heat transfer. Q. Are you an expert in air filtration?
7	report than deposition preparation?		•
		6	Q. Are you an expert in air filtration?
7	report than deposition preparation?	6 7	Q. Are you an expert in air filtration?A. I understand filtration quite well.
7 8	report than deposition preparation? A. That's correct. Yes.	6 7 8	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly
7 8 9	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more	6 7 8 9	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do.
7 8 9 10	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical	6 7 8 9	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing
7 8 9 10 11	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you	6 7 8 9 10 11	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter?
7 8 9 10 11 12	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology?	6 7 8 9 10 11 12	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to
7 8 9 10 11 12 13	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology? A. Correct.	6 7 8 9 10 11 12 13	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to my air pollution days, that was sort of what I was doing. Q. Okay. Have you ever conducted any
7 8 9 10 11 12 13 14 15	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology? A. Correct. Q. Do you have expertise in infectious	6 7 8 9 10 11 12 13 14 15	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to my air pollution days, that was sort of what I was doing. Q. Okay. Have you ever conducted any testing to determine the efficiency of an air
7 8 9 10 11 12 13 14 15 16	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology? A. Correct. Q. Do you have expertise in infectious diseases?	6 7 8 9 10 11 12 13 14 15 16 17	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to my air pollution days, that was sort of what I was doing. Q. Okay. Have you ever conducted any testing to determine the efficiency of an air filter used in a hospital?
7 8 9 10 11 12 13 14 15 16 17	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology? A. Correct. Q. Do you have expertise in infectious diseases? A. No.	6 7 8 9 10 11 12 13 14 15 16 17	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to my air pollution days, that was sort of what I was doing. Q. Okay. Have you ever conducted any testing to determine the efficiency of an air filter used in a hospital? A. No.
7 8 9 10 11 12 13 14 15 16 17 18	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology? A. Correct. Q. Do you have expertise in infectious diseases? A. No. Q. Do you have any expertise in aseptic	6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to my air pollution days, that was sort of what I was doing. Q. Okay. Have you ever conducted any testing to determine the efficiency of an air filter used in a hospital? A. No. Q. Do you consider yourself an expert in
7 8 9 10 11 12 13 14 15 16 17 18 19 20	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology? A. Correct. Q. Do you have expertise in infectious diseases? A. No. Q. Do you have any expertise in aseptic technique?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to my air pollution days, that was sort of what I was doing. Q. Okay. Have you ever conducted any testing to determine the efficiency of an air filter used in a hospital? A. No. Q. Do you consider yourself an expert in ASHRAE Standard 52.2?
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology? A. Correct. Q. Do you have expertise in infectious diseases? A. No. Q. Do you have any expertise in aseptic technique? A. No.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to my air pollution days, that was sort of what I was doing. Q. Okay. Have you ever conducted any testing to determine the efficiency of an air filter used in a hospital? A. No. Q. Do you consider yourself an expert in ASHRAE Standard 52.2? A. No.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology? A. Correct. Q. Do you have expertise in infectious diseases? A. No. Q. Do you have any expertise in aseptic technique? A. No. Q. Expertise in infection control	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to my air pollution days, that was sort of what I was doing. Q. Okay. Have you ever conducted any testing to determine the efficiency of an air filter used in a hospital? A. No. Q. Do you consider yourself an expert in ASHRAE Standard 52.2? A. No. Q. Do you have any expertise in
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology? A. Correct. Q. Do you have expertise in infectious diseases? A. No. Q. Do you have any expertise in aseptic technique? A. No. Q. Expertise in infection control practices other than as they relate to HVAC	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to my air pollution days, that was sort of what I was doing. Q. Okay. Have you ever conducted any testing to determine the efficiency of an air filter used in a hospital? A. No. Q. Do you consider yourself an expert in ASHRAE Standard 52.2? A. No. Q. Do you have any expertise in biomedical engineering?
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology? A. Correct. Q. Do you have expertise in infectious diseases? A. No. Q. Do you have any expertise in aseptic technique? A. No. Q. Expertise in infection control practices other than as they relate to HVAC systems?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to my air pollution days, that was sort of what I was doing. Q. Okay. Have you ever conducted any testing to determine the efficiency of an air filter used in a hospital? A. No. Q. Do you consider yourself an expert in ASHRAE Standard 52.2? A. No. Q. Do you have any expertise in biomedical engineering? A. No.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	report than deposition preparation? A. That's correct. Yes. Q. Okay. I want to talk a little more about your experience. Do you have any medical training? A. No. Q. You've already indicated that you don't have expertise in microbiology? A. Correct. Q. Do you have expertise in infectious diseases? A. No. Q. Do you have any expertise in aseptic technique? A. No. Q. Expertise in infection control practices other than as they relate to HVAC	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Are you an expert in air filtration? A. I understand filtration quite well. Relative to other people at ASHRAE who truly are experts, I do not know as much as they do. Q. Have you ever conducted any testing to determine the efficiency of an air filter? A. Well, if you go all the way back to my air pollution days, that was sort of what I was doing. Q. Okay. Have you ever conducted any testing to determine the efficiency of an air filter used in a hospital? A. No. Q. Do you consider yourself an expert in ASHRAE Standard 52.2? A. No. Q. Do you have any expertise in biomedical engineering?

Page 82 Page 83 1 1 **KOENIGSHOFER KOENIGSHOFER** 2 2 case, had you ever heard of a Bair Hugger? A. It's a large device that looks like a 3 3 A. Yes. refrigerator. Literally heats whatever's in 4 Q. How did you -- what do you recall 4 there, but they put blankets in there, I guess. 5 5 about Bair Huggers before you got into the O. Oh, okay. So this --6 litigation? 6 A. Wool blankets. I don't know what 7 7 A. I'm just very interested in they are. Cotton -- I don't know what they're 8 8 everything hospital. So when I would talk to made of -- blankets. 9 friends of mine or owners who work at 9 Q. I gotcha. So this -- this would be 10 10 hospitals, we'd talk about, you know, what some sort of a heater or heater storage for 11 exactly do they do in there? How does it all 11 normal cotton or wool blankets; is that right? 12 12 work? So someplace along the way, someone A. That's correct. 13 13 Q. It's not like an electric blanket mentioned a Bair Hugger. 14 14 Q. Did you ever have any conversations that you would put on an OR table? 15 15 with anyone before you got involved in this A. That's correct. I mean, it's 16 16 case about any concerns they had about the Bair electric. Uses electricity. You plug it in 17 Hugger and whether it was affecting the OR 17 the wall. You use electricity to make heat and 18 18 environment at their hospital? it heats however many blankets you've got 19 19 A. No. It was actually in the context stacked in this cabinet. 2.0 of are we going to put a blanket warmer into 20 Q. But the blankets themselves aren't 21 this OR? "Yes" or "no"? No, because we use 21 something that you --22 22 Bair Huggers. What's a Bair Hugger? A. Regular old blankets. 23 Q. It's not something you plug in? Q. Okay. So you mentioned a blanket 23 24 warmer. What would that be? As distinguished 24 A. No. 25 from the Bair Hugger, what's a blanket warmer? 25 Q. Okay. I think you mentioned earlier Page 84 Page 85 1 1 **KOENIGSHOFER** KOENIGSHOFER 2 2 with respect to patient-warming devices other A. No. I spent a lot of time on their 3 3 than the Bair Hugger, you did some research on website reading about nosocomial --4 4 the Mistral device? normothermia. 5 A. Yes. O. Okay. On the Mistral website? 6 Q. What did you look into with the 6 A. Yeah. They just had an article about 7 7 Mistral? it. 8 8 A. I simply was Googling around and came Q. Other than your reading of the 9 9 upon them as a, I guess, competitor. So I went Mistral article about normothermia, did you do 10 to their website and looked at what they sell, 10 any other research into normothermia? 11 what they do, their points of view. 11 A. No. I can't think that I read 12 Q. What did you learn from your research 12 anything else about it. 13 into Mistral? What stood out in your mind as 13 O. Do you have an understanding of the 14 relevant to your opinions in this case? 14 technical definition of normothermia versus 15 MS. ZIMMERMAN: Object to form. 15 hypothermia? 16 16 THE WITNESS: I would need to look at A. No. 17 17 -- you know, it's been -- this was back Q. Have you reviewed any literature that talked about the benefits of normothermia to 18 when I first started on this case, a year 18 19 or more ago. It seems to me I recall the 19 the patient? fact that they used a true HEPA filter in 2.0 20 A. Yes. Some of these articles that are 21 21 their device. truly about Bair Huggers or whatever, they kind 22 22 BY MR. GOSS: of start out with "why do Bair Huggers exist." 23 23 And they'll have a paragraph about Q. Anything about -- anything else about 24 24 the Mistral that stood out to you as normothermia. 25 25 noteworthy? Q. What's your understanding of the

Page 86 Page 87 1 **KOENIGSHOFER KOENIGSHOFER** 2 2 benefits to the patient of normothermia? wasn't really an outbreak. 3 3 A. Well --Q. Okay. It was one patient; right? 4 MS. ZIMMERMAN: Object to form. You 4 A. Yes. 5 5 can go ahead. Q. Have you ever worked with a hospital 6 THE WITNESS: I understand that that was investigating an outbreak or cluster 7 of infections? anesthesia, patients get cold, and for the 8 8 most part, anesthesiologists don't like A. No. 9 9 for the patients to get cold, and so it's Q. Do you have any expertise in the 10 10 beneficial to the patient to be kept warm. cleaning chemicals that are used to clean 11 BY MR. GOSS: 11 operating rooms? 12 12 Q. To your understanding, are there any A. No. 13 13 Q. Do you have any expertise in hospital benefits to the patient of normothermia, beyond 14 14 sanitation and hygiene practices other than comfort? 15 15 A. I believe that I have read that, you HVAC? 16 16 know, the outcomes are improved by not letting A. About this much (indicating). 17 17 Q. What can you tell me that you know the body get too cold. 18 18 Q. But at any rate, you're not an expert about that? 19 19 in temperature regulation of the human body? A. Well, I understand that there's 2.0 A. I am not a biological expert. 20 something called a terminal clean, which is, in 21 my limited understanding, is a super-deduper 21 Q. Have you ever participated in an 22 22 cleaning, which is different than -- I didn't investigation of an infectious outbreak at a 23 hospital? even know the name of a nonterminal clean. 2.4 24 That's kind of everything I know about it. A. Well, that expert witness case that I 25 25 Q. You've designed HVAC systems for was on. I guess you could say it was. It Page 88 Page 89 1 **KOENIGSHOFER** 1 **KOENIGSHOFER** 2 2 operating rooms; correct? surgery OR? 3 A. Yes. A. Some clients insist on using HEPA 4 4 Q. About how many would you say you've filtration, although it's not required. One of 5 5 done? the studies I did was on, the surgeons wanted 6 to put curtains around the diffuser array. And 6 A. Well, from scratch, maybe 20. 7 Q. Were any of those ORs dedicated to they asked me to give them a little study of 8 8 orthopedic surgery? pros and cons of that. It was an orthopedic 9 9 A. You know, my mind goes fuzzy between surgery -- orthopedic OR. 10 things that I designed and places that I worked 10 Q. The curtain, was it an air curtain or 11 11 to try to improve conditions. a fabric curtain? What kind of curtain was it? 12 Q. Okay. Well, let's include both in 12 A. Plexiglass. 13 13 your answer. Q. Okay. So it was a Plexiglass curtain 14 A. Okay. Then yes. 14 around --15 15 Q. How many orthopedic ORs have you A. More of a barrier. 16 16 either designed or worked to improve in some Q. A barrier around the diffusers and 17 17 way? the ceiling of the OR? 18 A. Let's just say 15. 18 A. Yes. 19 Q. Is there a difference in your 19 Q. And was this an orthopedic group that 2.0 20 approach to the HVAC system for a general wanted to do this? 21 21 surgery OR versus an orthopedic OR? A. It was a hospital that -- but it was 22 A. No. 22 an orthopedic surgery unit. It wasn't a 23 23 private orthopedic group was the distinction Q. So your approach is the same. Is 24 24 there anything different in the execution of I'm making there. 25 25 the design of an orthopedic OR versus a general Q. So it was for a hospital, but the

Page 90 Page 91 1 1 KOENIGSHOFER **KOENIGSHOFER** 2 2 room was going to be for their orthopedic unit? MS. ZIMMERMAN: Object to form. 3 3 A. Yeah. Well, it already was, but they BY MR. GOSS: wanted to add the Plexiglass barrier. 4 Q. In the context of a hospital and air 5 5 Q. Was there a particular manufacturer supply from the ceiling. 6 of the Plexiglass barrier or was it part of an 6 A. Well, in the context of a hospital, 7 7 integrated system with diffusers? we put in diffusers, which literally in the 8 8 industry are called "laminar flow diffusers." A. Yes. And I don't remember the name 9 9 It is a type of a diffuser, which consists of of the manufacturer. 10 Q. What was your advice to the hospital 10 big metal covers with a bunch of small holes in 11 of the use of this Plexiglass barrier? 11 them, and the air gently flows down in kind of 12 A. I recommended that it was not cost 12 a rainfall pattern. 13 13 Q. So what makes it laminar? effective. 14 14 MS. ZIMMERMAN: Object to form. O. What was the rationale behind the 15 Plexiglass barrier? What it was supposed to 15 THE WITNESS: Well, it is released in 16 16 a strictly vertical manner and at a speed 17 17 that, as I say, you -- 35 feet a minute A. Well, it was supposed to improve the 18 laminar flow of the air as it comes from the 18 makes basically a maximum velocity at the 19 diffuser. Keep it as straight as you can as 19 diffuser. And so you hope that it just 20 2.0 stays together as a laminar flow. long as you can. So they would stick down, I 21 don't know, maybe 18, 24 inches, something like 21 BY MR. GOSS: 2.2 22 that. Q. Okay. Do the -- do the holes in the 23 23 diffuser outflow, does that have something to Q. So let me ask you some questions 2.4 24 about that statement. When we say "laminar do with what makes it laminar? 25 25 flow," what are we really talking about? MS. ZIMMERMAN: Object to form. Page 92 Page 93 1 KOENIGSHOFER 1 KOENIGSHOFER 2 2 Foundation. State gurus in this kind of stuff. And they 3 THE WITNESS: Well, yeah. You've got say it's not really laminar flow. And I say, 4 4 to give it a little kick in the butt to okay, okay, okay. But we engineers call it 5 5 get the air moving. 6 BY MR. GOSS: 6 Q. All right. So do you know the names 7 Q. Would it be fair to say that you're 7 of any of the -- can you remember the names of 8 8 not an expert in laminar flow? any of the laminar flow gurus that you've 9 9 A. Yeah. Yes. spoken to about this? 10 10 Q. I think there was a comment in your A. No, not really. This is a long time 11 11 report and a footnote on page 13. So there's a ago. There was a guy from Penn State, but I 12 sentence in the first paragraph. It says, "As 12 can't remember. 13 shown in the following figure, clean air is 13 Q. It wasn't Gary Settles? 14 directed into the room through so-called 14 A. No, no, no. It was not Gary Settles. 15 15 laminar diffusers." And then there's a He probably would -- he could probably answer 16 16 footnote; right? this question. 17 17 A. Yes. Q. Let's see. All right. So we started 18 Q. The footnote says, "This intentional 18 on this tangent about laminar flow when we were 19 airflow is frequently called laminar, though 19 talking about this system that you were asked 20 2.0 to advise the hospital on that had these the airflow is not truly laminar from a physics 21 21 perspective." What did you mean by your Plexiglass barriers; right? 2.2 statement in the footnote? 22 A. Uh-huh. 23 23 Q. Okay. And your advice to the A. Well, to be honest, I'm just 24 24 hospital was that the system was not cost repeating what true laminar flow experts have 25 25 said to me, guys who are, you know, Ph.D Penn effective; is that right?

	Page 98		Page 99
1	KOENIGSHOFER	1	KOENIGSHOFER
2	BY MR. GOSS:	2	again.
3	Q. I just want to know his answer to the	3	BY MR. GOSS:
4	question. Would you be able to answer that	4	Q. Sure. How would you describe or can
5	question?	5	you answer the question, what the difference is
6	A. Yes.	6	between a turbulent supply system in an
7	Q. And how would you answer that	7	operating room and a laminar supply system?
8	question?	8	A. Yes. And that's that was my my
9	A. I would probably get a piece of paper	9	hand drawings.
10	and indicate air moving unidirectionally as	10	MS. ZIMMERMAN: And if we could just
11	opposed to turbulently.	11	clarify for the record and the court
12	Q. Okay. And what about systems that	12	reporter that the witness is gesturing
13	deliver laminar flow versus turbulent flow? Do	13	with his hands.
14	you have any expertise in the difference	14	THE WITNESS: Vertical airflow fairly
15	between those types of systems?	15	tight.
16	A. Well, yes. I mean, I could design	16	BY MR. GOSS:
17	this room, and this diffuser right here works	17	Q. Okay. You've never calculated a
18	on the basis of turbulence. That's what it	18	Reynolds number; is that true?
19	depends upon.	19	A. I have in college.
20	Q. But in terms of operating room air	20	Q. Is calculating a Reynolds number part
21	supply, do you have expertise in the difference	21	of what you do in your engineering practice
22	between a turbulent diffuser versus a laminar	22	when working with hospitals?
23	one?	23	A. No.
24	MS. ZIMMERMAN: Object to form.	24	Q. Have you tried to calculate a
25	THE WITNESS: Ask me the question	25	Reynolds number for any of your work in this
	THE WITH ESST TISH HIS UNG QUESTION		
	Page 100		Page 101
1	KOENIGSHOFER	1	KOENIGSHOFER
2	case?	2	Q. When was that?
3	A. No.	3	A. In March.
4	Q. What are the issues that you've been	4	Q. Was that during the meeting with
5	asked to address in this case?	5	counsel?
6	A. I guess just the overall use of the	6	A. Yes.
7	Bair Hugger in an operating room.	7	Q. Outside of that meeting, have you
8	Q. Have you done any experiments to	8	seen a Bair Hugger unit in person?
9	address that question?	9	A. I'm sure I've seen them when I've
10	A. No.	10	been in operating rooms.
11	Q. Have you taken any measurements of	11	Q. But fair to say you didn't examine
12	air temperature or velocity coming out of a	12	them closely in that setting?
13	Bair Hugger blanket?	13	A. Correct.
14	A. No.	14	Q. When you saw the Bair Hugger unit in
15	Q. Have you done any experiments to	15	March, how was it set up?
16	determine the efficiency of Bair Hugger	16	A. Just sitting on the floor.
17	filters?	17	Q. Was it connected to a blanket?
18	A. No.	18	A. No.
19	Q. Have you done any testing	19	Q. Did you do anything with the Bair
20	measurements or experimentation of any kind on	20	Hugger unit when you saw it?
21	a Bair Hugger unit?	21	A. I took the cover off so I could see
22	A. No.	22	inside.
23	Q. Have you seen a Bair Hugger unit in	23	Q. Did you turn it on?
24	person?	24	A. I don't think so.
2.1			
25	A. Yes.	25	Q. And you said it was not connected to

Page 102 Page 103 **KOENIGSHOFER** KOENIGSHOFER 2 2 a perforated blanket; is that right? A. Uh-huh. 3 3 Q. And a fan? A. That's correct. Q. Have you ever felt the flow of air 4 A. And a fan. 5 from a Bair Hugger blanket? 5 Q. Does your wife's hair dryer have a 6 6 A. No. filter? 7 7 Q. Have you ever felt the flow of air A. No. 8 8 from a Bair Hugger hose that's not connected to O. So that would be one difference? 9 9 a blanket? A. Sure. 10 10 A. No. Q. So the Bair Hugger that you examined 11 11 Q. So when you say you took the cover was -- that wasn't in an OR at the time; right? 12 off of the Bair Hugger, what was your goal in 12 A. Correct. 13 13 doing that? Q. And if you didn't turn it on, is it 14 14 fair to say that you didn't evaluate whether A. See the insides. 15 Q. Was there anything that stuck out in 15 the air from the Bair Hugger was doing anything your mind as significant from your looking on 16 16 to the air in the room? 17 the inside of a Bair Hugger unit? 17 That's correct. 18 18 MS. ZIMMERMAN: Object to form. Q. Do you remember what model of Bair 19 BY MR. GOSS: 19 Hugger it was? 2.0 Q. What did you take away from that, is 20 A. I think it was early in the 500 21 21 what I'm asking. series, I believe. 22 2.2 A. It looked just like my wife's hair Q. Do you remember if it was white or 23 dryer that I tried to fix recently. 23 kind of blue/purple? 24 2.4 Q. So it had a heating coil in it; A. I think it was white. 25 25 Q. Did you take the filter out of that correct? Page 105 Page 104 1 1 **KOENIGSHOFER KOENIGSHOFER** 2 2 Bair Hugger? Q. Do you have any understanding as to 3 3 whether the filter media in the cylindrical and A. I don't remember. 4 4 Q. Do you remember what the filter the rectangular filters was different at some 5 5 looked like, like what shape it was? time in the past, that they differed from each 6 A. Yeah. I think it was one of the flat 6 other? 7 7 rectangular ones. A. You know, it seems like in the Van 8 8 O. Did you take the filter out and Duren or something, there was conversations 9 9 examine it? about this, but sitting here right this minute, 10 10 I don't remember. We could look at Van Duren. A. Honestly, I don't remember whether I 11 11 did or did not. I believe it was Van Duren that said something 12 12 Q. You mentioned this filter was a flat about that I think there were some changes 13 13 rectangular one. Are you familiar with other along the way. 14 shapes or sizes of Bair Hugger filters? 14 Q. Do you intend to testify at trial 15 15 A. Oh, again, I've seen on the exploded about changes in the filter media in the Bair 16 16 views that they have cylindrical ones. Hugger units? 17 17 Q. Other than the shape of the filter A. I don't know. 18 being different between the cylindrical and the 18 O. Do you -- do you have any opinions 19 rectangular, do you have any understanding as 19 today about changes in the filter media in the 2.0 20 to whether the filter media in those two Bair Hugger filters? 21 21 filters is different as of today? A. No. 22 A. Is different between a rectangular 22 Q. So you've seen a Bair Hugger unit. 23 23 Have you ever seen a Mistral unit in versus the cylindrical? 24 24 Q. Yes, sir. person? 25 25 A. I don't know. A. No.

Page 106 Page 107 1 **KOENIGSHOFER** 1 **KOENIGSHOFER** 2 2 devices? Q. Have you ever seen any other 3 3 patient-warming devices in person? MS. ZIMMERMAN: Object to form. A. No. 4 THE WITNESS: I am not aware of any. 5 5 Q. Are you familiar with a device called BY MR. GOSS: 6 6 Q. Are you aware of any requirements or the HotDog? 7 7 A. Only from the materials that I read any regulations or standards that require the 8 8 use of filtration in hospital equipment, other in relation to this case. 9 than the HVAC system? Q. What's your understanding of what the 10 10 HotDog is and how it works, if you have one? MS. ZIMMERMAN: Object to the form of 11 11 A. It appears to me it's an electric the question. 12 12 THE WITNESS: I'm not aware of any. blanket. 13 13 BY MR. GOSS: Q. Have you done any research for this 14 14 case on the HotDog warming system? O. So for -- strike that. 15 A. I've looked at their website. I 15 Are you familiar with the types of 16 16 would not call it research. infections that the -- no, back up. 17 17 Q. For your work on this case, have you Are you familiar with the types of 18 18 done any research on standards or regulations surgeries that the plaintiffs in this 19 19 that apply to patient warming devices? litigation have undergone? 20 MS. ZIMMERMAN: Object to form. 20 A. Well, in a general way, yes. My 21 21 THE WITNESS: Can you ask me the father-in-law just had a knee replacement. And 22 2.2 I've looked at the -- a YouTube of a hip question again. 23 BY MR. GOSS: 23 replacement. 24 2.4 Q. Sure. Are you aware of any standards Q. And when you say the YouTube hip 25 25 replacement, are you referring to a particular or regulations that apply to patient-warming Page 108 Page 109 1 **KOENIGSHOFER** 1 KOENIGSHOFER 2 2 video? country? 3 A. Somewhat, yes. But then you're going A. I wouldn't know. I mean, it was one 4 4 of those days where you're just fishing all to ask me for the numbers. 5 around the internet and you find something. It Q. Yes, sir. What's your understanding 6 6 was not one put out by -- it was more of a of the current infection rate for hip 7 procedures in this country? training for medical people. 8 8 Q. Did it relate to the Bair Hugger at A. I would really have to look at my 9 9 all? booklet here. 10 1.0 MS. ZIMMERMAN: You can look at your A. No. 11 11 Q. All right. So do you have an notes 12 12 understanding that the majority of the THE WITNESS: If he wants me to do 13 13 plaintiffs in this litigation have undergone that, I'll do that. 14 either a hip replacement or a knee replacement? 14 MR. ASSAAD: Do it if you want to. 15 15 A. Yes, I know that. BY MR. GOSS: 16 Q. And have you requested any 16 Q. Do you have a general understanding 17 17 information about the types of infections that of the infection rate for hip and knee 18 these plaintiffs have developed as a result of 18 replacements? Do you remember a figure? 19 19 A. I think it's generally in the range those procedures? 2.0 20 of 1 to 3 percent. A. No. 21 Q. In association with those procedures? 21 Q. Do you have an understanding as to 22 A. No. 2.2 whether that rate has increased, decreased or 23 23 stayed the same over the last 10 years? Q. Do you -- for your work on this case, 24 24 A. I believe -- well, I read a lot of did you do any research into the rate of 25 25 infection for hip and knee replacements in this articles and one guy says one thing and the

Page 126 Page 127 1 **KOENIGSHOFER** KOENIGSHOFER 2 2 to some of the addenda that have come out more THE WITNESS: Yes. 3 3 BY MR. GOSS: recently. I don't know how many addenda you 4 have on this thing right here. They come out 4 Q. And that's something that a hospital 5 5 looking to comply with Standard 170 is going to every month, every other month. 6 Q. What -- what addenda do you recall 6 be interested in as best practices for 7 7 contributing to? What was the subject matter ventilation of healthcare facilities; correct? 8 8 MS. ZIMMERMAN: Object to form. of the addenda? A. The subject -- well, of addenda that 9 Foundation. 10 have been adopted? I would really have to 10 THE WITNESS: Again, you asked me 11 refer back to my notes on that one to remember 11 about hospitals. I can't speak. There 12 which one, to which it applied. 12 are 10,000 people that work at a hospital. 13 Q. Is it your testimony that ASHRAE 170, 13 BY MR. GOSS: 14 14 Standard 170 has nothing to do with the best Q. Well, you've worked with a lot of 15 practices for HVAC design in healthcare 15 hospitals over the years, have you not? 16 16 facilities? A. I have. 17 17 MS. ZIMMERMAN: Object to form. Q. And those hospitals are interested in 18 18 your expertise on best practices; correct? Misstates his testimony. 19 THE WITNESS: I would not make that 19 MS. ZIMMERMAN: Object to form. 2.0 20 BY MR. GOSS: statement. 21 BY MR. GOSS: 21 Q. In HVAC design for the ventilation of 22 22 healthcare facilities; true? Q. Okay. So it does have something to 23 do with best practices in the ventilation of 23 A. Yes. 2.4 healthcare facilities; is that right? 24 Q. All right. 170 covers a wide range 25 25 of topics, but one of the topics that's MS. ZIMMERMAN: Object to form. Page 129 Page 128 1 KOENIGSHOFER 1 **KOENIGSHOFER** 2 2 covered, of course, is filtration; correct? A. I know something about it, yes. 3 3 A. Yes. Q. Are you familiar with the ASHRAE 4 4 Q. All right. And if you look at table standard for calculating MERV ratings for air 6.4. it discusses minimum filter efficiencies? 5 5 filters? 6 6 A. Yes. A. In a general way. I'm not on 7 7 Q. On page 5; correct? Standard 52. 8 A. Yes. Q. But it's Standard 52.2; correct? 9 9 Q. It says, "Operating rooms for Class B A. 52.2, I believe that's the latest. 10 and C surgery require, in filter bank number 1, 10 Q. All right. So coming back to this a MERV 7 filter and in filter bank 2, a MERV 14 11 11 table 6.4, is it fair to say that filter bank 12 number 2 in this table, is that the terminal 12 filter: is that correct? 13 13 A. Correct. filtration? In other words, the last filter 14 14 Q. All right. First of all, let's before the air goes to the room? 15 15 explain what MERV is. What does that stand A. It's the last filter in the system. 16 16 for? Q. In the system. And this provides for 17 17 A. Well, it's something like minimum a MERV minimum of 14; correct? 18 efficiency -- always forget exactly what MERV 18 A. Correct. 19 stands for. It has something to do with 19 Q. Have you ever taken a position in any 2.0 20 minimum efficiency rating value or something committee meetings for 170 that that value 21 21 like that. should be higher? 22 Q. And do you know how MERV --22 A. I've certainly been involved in a lot 23 23 A. Minimum Efficiency Reporting Value. of discussions about it. 24 Q. Okay. Do you know how MERV ratings 24 Q. Have you personally recommended to 25 25 are calculated for air filters? the committee that the final filter in the

Page 130 Page 131 1 1 **KOENIGSHOFER KOENIGSHOFER** 2 2 system for an operating room -- for -- should prevent an orthopedic room from doing that; 3 3 be higher than 14? correct? 4 A. Not for a general operating room. 4 A. That's correct. 5 5 Q. What about other than for a general Q. In your -- in the various meetings 6 6 you've attended for Standard 170, do you have operating room? 7 7 any understanding as to whether the committee A. I have suggested that maybe we should 8 8 start requiring it for orthopedic operating intends to increase the minimum filter 9 9 requirements for Class B and Class C surgery? 10 Q. And you suggested this during a 10 MS. ZIMMERMAN: Object to form. 11 11 committee meeting of -- of the 170 Committee? THE WITNESS: Among the addenda on 12 12 the table at this time, that is not one of A. Yes. 13 Q. Did you make that recommendation --13 them. 14 14 when do you recall making that recommendation? BY MR. GOSS: 15 A. As Jim said, I've been going to these 15 Q. Where it says "Class B and Class C 16 16 meetings for 14 years, two or three a year for surgery," am I correct that orthopedic surgery 17 17 14 years. I honestly can't remember at what would be encompassed within one of those 18 18 point. classes? 19 Q. Was it in the last two years? 19 A. Yes. 2.0 2.0 A. I would say probably before that. Q. Which one is it? 21 Q. Has it been your experience that 21 A. It's probably the Class C, I would 22 22 orthopedic rooms sometimes do incorporate HEPA assume. 23 filters? 23 Q. And the only space designation on 24 2.4 this table 6.4 that calls for HEPA is a A. Yes. 25 25 Q. And nothing in this table would protective environment room; correct? Page 132 Page 133 1 1 KOENIGSHOFER **KOENIGSHOFER** 2 2 A. That's correct. information, see Memarzadeh and Manning 2002, 3 3 and Memarzadeh and Jeong in informative Q. And this protective environment room, 4 4 is that where you put someone who is contagious appendix B." Are you familiar with the 5 Memarzadeh and Manning paper on this subject? with a respiratory illness, for example? 6 6 A. No, just the opposite. A. Yes. 7 7 Q. It's where you put somebody who's Q. So what is -- what is the reason that 8 8 susceptible that you need to protect? Memarzadeh and Manning gave for setting the 9 9 A. Correct. airflow volume and velocity at 25 to 35 CFMs 10 10 per square foot? Q. Okay. Are the HEPA filters in 11 11 protective environment rooms, are they on the A. Well, it was to get adequate air 12 changes, 20 per square foot -- I'm sorry, 20 12 inflow to the room or the outflow from the 13 13 room? air changes per hour. And given the size the 14 A. Inflow. 14 laminar diffuser is going to be, roughly the 15 15 size of the table plus a foot or two on each Q. If you'll turn with me to page 14, 16 16 section 7.4 talks about surgery rooms. And if side, you have to have a certain amount of 17 17 you look at point A, it says, "The airflow airflow to get those air changes. 18 shall be unidirectional downwards and average 18 Q. Okay. But is there something about 19 velocity of the diffuser shall be 25 to 19 this particular velocity that's important, the 2.0 2.0 35 cubic feet per minute per square foot." 25 to 35 CFMs? 21 21 Are you familiar with that A. Memarzadeh hypothesized about a wound 22 requirement for the face velocity or volume 22 plume. 23 23 metric flow out of the diffusers? O. Tell me about that. What does he 24 24 mean by "wound plume"? A. Yes. 25 25 Q. And it says here, "For further MS. ZIMMERMAN: Object to form.

Page 210 Page 211 1 1 **KOENIGSHOFER** KOENIGSHOFER 2 2 THE WITNESS: I wouldn't say that. BY MR. GOSS: 3 3 BY MR. GOSS: Q. Well, the results did not reveal any 4 Q. All right. How would you say it? 4 statistically significant correlation between 5 5 A. If the number of particles is low, microbial loads and particle counts for either 6 the probability is that the number of 6 of the particle diameters considered; correct? 7 7 colony-forming units is also low. A. That's what it says, yes. 8 8 Q. And now, are you saying conversely, Q. All right. And the Landrin article 9 that if the particle count is high that there 9 also found that no particle count value could 10 10 is a correlation of some sort to airborne be predictive of a microbial count higher than 11 11 bioburden? 5 CFUs per metered cube; correct? 12 12 A. Predictive. In other words, you A. I believe there is, yes. 13 MS. ZIMMERMAN: Objection. 13 would have trouble drawing a -- a line on a 14 Q. How would you show that graph. 15 scientifically? 15 Q. What --16 A. Some correlation. 16 A. Does more equal more? He didn't 17 Q. Okay. 17 exclude that as a possibility. 18 A. Well, I mean, the efforts that these 18 Q. As a possibility, but what would you 19 different people are making. I mean, they 19 rely on to make a correlation? What research 2.0 didn't say there was no correlation. 20 or article would you rely on to make 21 Q. No statistically significant 21 a correlation that particle count is an 22 correlation; correct? 2.2 appropriate surrogate for bioburden? 23 A. Within the size ranges that they're 23 A. Well, first of all, I'd rely on 24 2.4 discussing. common sense. 25 MS. ZIMMERMAN: Object to form. 25 Q. Okay. Page 212 Page 213 1 1 KOENIGSHOFER **KOENIGSHOFER** 2 2 A. I think that some number of particles BY MR. GOSS: 3 3 in the air are going to have bacteria on them. Q. Is that fair? 4 4 O. No dispute there. MR. GOSS: I'm not asking his 5 5 But the correlation between the testimony. I'm asking him a question. 6 6 number of particles and the number of bacteria, BY MR. GOSS: 7 7 what do you rely on in terms of your role as an Q. Can you tell me right now of any 8 8 study that correlates airborne particles to expert witness in this case to make that 9 9 correlation? actual bioburden in an operating room? 10 10 MS. ZIMMERMAN: Well, respectfully, A. For example, in the standard USP 797, 11 11 they talk about CFUs per particles. counsel, he's not required to have every 12 12 study memorized that he's looked at. Q. Okay. And that's US Pharmacopeia? 13 13 A. Yes. MR. GOSS: I understand that. I'm 14 14 just asking him if he knows it or he Q. For a pharmacy? 15 15 A. Yes. doesn't. 16 Q. Are you aware --16 BY MR. GOSS: 17 17 A. I've seen other articles on it. Q. I'm not saying no such studies exist. 18 18 A. I believe that I have seen such Again, I can find it here. I think I have one 19 19 here. statement in some of these studies that are in 2.0 2.0 Q. But as of right now, you can't point this binder right here. 21 21 me to anything that correlates particles to Q. Would it be fair to say that the 22 bioburden in an operating room? 22 literature regarding the correlation between 23 23 MS. ZIMMERMAN: Objection to form. particle counts and airborne bioburden is mixed 24 24 in terms of some find correlation and some Misstates his testimony. 25 25 don't?

Page 226 Page 227 1 **KOENIGSHOFER** 1 **KOENIGSHOFER** 2 2 infections. So when I say it's 5 to 15 -- if earlier, if so I apologize. 3 3 you dug into the CDC data it may show you. Have you tested a Bair Hugger unit 4 for leaks around the filter? 4 Whether some are shallow, some are deep, I 5 5 A. No. don't really know. 6 Q. Page 13. It discusses the role of Q. So your statement here is based more 7 7 site in the infection equation. And the third just on your experience? 8 8 sentence is, "Deep wounds are generally A. Yes. 9 9 understood to be more susceptible than shallow Q. The last sentence in that paragraph 10 10 wounds." you're talking about the space below the OR 11 11 diffusers. The area directly below the What's that comment based on? 12 12 A. Oh, I guess it is based on, you know, diffuser is referred to as the sterile field; 13 13 the reading that I've done. And again, common correct? 14 sense and the fact that, I mean, I know of A. It is referred to by us design 15 15 people -- well, I've read of people who will engineers as the sterile field, yes. 16 16 get wounds -- I mean, infections in hip and Q. I want to make sure I understand why 17 17 knee replacements, and it lasts for years and it's referred to as the sterile field. Is it a 18 18 years and years. sterile field because the air coming down is 19 19 Q. Yeah. sterile, or is it because the surgical site has 20 A. It's obviously very, very serious. 20 been prepared using cleansers and --21 21 Q. Do you have any understanding of the A. I'm speaking as a design engineer, 22 22 rate of superficial surgical site infections, and it's the air coming down. Is it 23 meaning around the skin and the incision? 23 100 percent sterile? No. 24 A. You know, I don't know the breakdown 24 Q. And then you say, "Anything that 25 25 disrupts this waterfall of sterile air reduces of those percentages of hospital-acquired Page 229 Page 228 1 1 KOENIGSHOFER KOENIGSHOFER 2 2 its effectiveness. Disruptions, turbulence are A. Well, I have had clients who want 3 3 caused by surgeons and staff, objects, light more and there are probably clients who want 4 4 less. But we never do less because that's what booms, tables, thermal plumes, markedly hot or cold air, and air currents caused by devices, 5 the code is. 6 personnel and doors;" correct? 6 Q. So is it fair to say that 2000 to 7 7 3000 CFMs is fairly typical for operating rooms A. Yes. 8 in the U.S., based on your experience? Q. And all of those things can be 9 9 present in an operating room with or without A. Yeah. I mean, it depends on the size 10 the Bair Hugger; correct? 10 of the operating room -- the size of the 11 11 A. That's correct. operating room, the volume. 12 BY MR. GOSS: 12 Q. Page 14 you talk about the element of 13 13 time in the infection equation. Q. Okay. 14 A. That's what you're doing. You're A. Yes. 15 changing out the volume of the operating room 15 Q. And this is where you discuss the 16 16 20 ACH requirement from Standard 170. And you 20 times per hour. So flow rate in is 17 17 say, "In most ORs this is a flow rate of 2000 determined by what's the volume of the 18 operating room. 18 to 3000 CFMs: correct? 19 Q. And the flow rate out of the Bair 19 A. Yes. 20 Hugger blankets, what is that figure? 20 Q. And I think you mentioned earlier 21 21 that some hospitals may want a flow rate that's A. About 50. 22 2.2 Q. About 50 for the 750, 775 and higher or lower than that; correct? 23 something lower than that for the 505; correct? 23 MS. ZIMMERMAN: Object to form. 24 24 A. That's correct. BY MR. GOSS: 25 25 Q. Or is that true? Q. Page 15 you have the -- the top

Page 238 Page 239 KOENIGSHOFER **KOENIGSHOFER** 2 2 surgical site, would actually lead to an MS. ZIMMERMAN: Object to form. 3 3 THE WITNESS: I certainly could not, increased risk of surgical site infection." with the data that is in front of me. 4 Based on your review of this data, do 4 5 5 you agree with their conclusion? BY MR. GOSS: 6 MS. ZIMMERMAN: Object to the form of Q. Okay. Do you recall encountering a 7 7 the question. The article speaks for study in your review of the literature that 8 8 showed bacteria detected -- sorry, let me try itself. 9 9 BY MR. GOSS: again. 10 Do you recall seeing a study that 10 Q. What's your opinion of the data 11 11 and -- and their conclusion? Do you disagree found bacteria emitted from the Bair Hugger 12 with -- how they interpret it? 12 blanket? 13 13 MS. ZIMMERMAN: I will object to the A. I saw one that had Bair Hugger --14 14 form to the extent that it suggests that bacteria from Bair Hugger hose. 15 the witness has been provided the actual 15 Q. Okay. Was that Avidan? 16 16 data, but you can answer the question A. Well, there's this one, and there's 17 17 about the author's interpretation. also a guy -- is this the one where he did the 18 18 swabs? Because there's also one where a guy BY MR. GOSS: 19 19 Q. And just limited to what's in the swabbed the hoses too. 2.0 20 Q. Let's take a look. paper. 21 21 A. This is agar plate, so I guess he was A. He's simply saying he can't make a 22 22 conclusion. just blowing air. 23 23 Q. Are you looking at Avidan? Q. Right. And looking at this data, do 2.4 you think that you can make a conclusion that 24 A. This is Avidan. 25 25 he didn't? MR. GOSS: Okay. Let me go ahead and Page 240 Page 241 1 1 KOENIGSHOFER **KOENIGSHOFER** 2 2 plates;" correct? mark an exhibit. 3 (Thereupon, Exhibit 20 was marked for A. Um-hmm, yes. 4 4 identification.) Q. And then the machine was turned on to 5 5 BY MR. GOSS: blow air at 43 degrees c over the plates for 6 Q. Is the copy -- is Exhibit 20 the same 6 five minutes. 7 7 as the copy you have in your notebook? 40 centimeters, how -- roughly how 8 8 A. Yes. high is that? Is it --9 9 Q. It's the same study anyway. A. Well, two and a half centimeters is 10 A. Yes. Mine is printed better than 10 an inch, so it's, what, 12 inches or something. 11 yours. It's easier to read. 11 Q. Okay. All right. 12 Q. That's fair. That's fair. 12 A. Fourteen. 13 13 MS. ZIMMERMAN: Bigger font; right? Q. Okay. So a little more than a foot 14 THE WITNESS: So Avidan did both. He 14 off of the agar plates? 15 15 did the agar test as well as swabbing the A. Uh-huh. 16 16 hoses. Q. Okay. With that setup would it be 17 17 BY MR. GOSS: possible for room air to be entrained in the 18 18 Q. All right. And with respect to the flow from the hose? agar plates, if you go to page 1074, the second 19 19 MS. ZIMMERMAN: Object to the form of 20 2.0 the question. Foundation. page says at the top, "Experiment 1: Are 21 21 microbes present in the airstream of warmers?" THE WITNESS: You know, anything is 2.2 It says, "Each warmer was placed 22 possible. I have not calculated what the 23 23 sequentially on a standard place on the floor. velocity of the air is from a Bair Hugger 24 24 The nozzle of the hose was suspended from an hose. 25 2.5 infusion stand 40 centimeters above two agar

Page 242 Page 243 1 1 **KOENIGSHOFER KOENIGSHOFER** 2 2 BY MR. GOSS: is true. I don't see in my --3 3 Q. The distance? Q. Okay. 4 A. As I think about it, 40 centimeters, 4 A. -- in my 10 seconds of reading here 5 5 that it says what the distance was between the that's -- that's a half a meter almost, so it's 6 6 probably more like 18 inches. But anyway -plate and the blanket. 7 7 Q. Okay. Q. Okay. I don't think it does say, but 8 8 A. That order of magnitude. you're welcome to look. 9 9 Q. Okay. In other words, the hose But at any rate, as you observed in 10 10 your report, when they had the blanket attached wasn't blowing directly on to the plate. It 11 was --11 to the hose, they did not detect CFUs on the 12 12 A. Yeah. agar plates; correct? 13 13 Q. -- half a meter roughly from -- from A. That is what they did in their 14 the plates; correct? report -- reported from their report, yes. A. Yes. 15 Q. Okay. And that's .5b in your report, 15 16 16 Q. All right. And they detected correct, on page 17? 17 bacteria in some of the plates when they did 17 A. Yes. 18 18 that experiment; correct? Q. If you turn to page point F, 5F, 19 19 A. They did. about Avidan, you mention that, "Recommend 2.0 Q. But then they did a different 20 always use perforated blankets and microbial 21 experiment with agar plates under the Bair 21 filter on hose, ensure hoses are sterilized 22 22 Hugger blanket; correct? regularly." 23 23 A. Blankets were elevated over the agar With respect to perforated blankets, 24 plates. Doesn't say what the distance was 24 is it your understanding that -- or do you have 25 there. I mean, in general, yes, what she said 25 an understanding as to whether 3M instructs Page 245 Page 244 1 KOENIGSHOFER 1 **KOENIGSHOFER** 2 2 users to always have the hose attached to a box. 3 3 blanket during use? Q. Okay. 4 4 A. Presumably from the heating elements, MS. ZIMMERMAN: Object to form. And I don't know where within, but... 5 foundation. 6 6 Q. Was it -- was the source past the BY MR. GOSS: 7 7 Q. Did you review the operator's manual intake filter? 8 during your work in this case? A. It was. 9 9 A. Yes, I did. And yes, it does. O. Okay. So in other words, the soot 10 Q. Okay. So that's Avidan. 10 was generated inside the machine post filter; 11 Do you recall -- and Avidan did not 11 correct? 12 12 find bacteria emitted from the blanket; MS. ZIMMERMAN: Object to form. And 13 13 correct? foundation. 14 14 BY MR. GOSS: A. Correct. 15 15 Q. Did you find any studies that found Q. If you know. If you remember. 16 16 A. I would have to make that assumption bacteria emitted from the blanket? 17 17 because there's almost nothing before the A. I found a study where soot was 18 18 ejected from a blanket. filter. All the mechanisms are after the 19 19 Q. Okay. Is soot the same as bacteria? 20 20 A. It is not. Q. Right. Right. Do you have an 21 Q. In that paper where was the soot understanding -- or let me ask you this. Have 2.2 coming from? 2.2 you tried to measure the size of the pinholes 23 23 A. From the Bair Hugger. perforations in the Bair Hugger blanket? 24 Q. What part of the Bair Hugger? 24 A. I have not. 25 25 A. From the -- well, the box, the black Q. Do you have an understanding of how

	Page 254		Page 255
1	KOENIGSHOFER	1	KOENIGSHOFER
2	A. Yes.	2	A. What page is it?
3	(Thereupon, Exhibit 22 was marked for	3	Q. Twenty-two.
4	identification.)	4	Okay. Do you have a copy of Galson
5	BY MR. GOSS:	5	and Goddard, the paper itself? I tried to find
6	Q. All right. Is this the same Kowalski	6	it online and it wasn't available.
7	paper that you discussed?	7	MS. ZIMMERMAN: 1968?
8	A. Yes.	8	THE WITNESS: Yeah. I think that I
9	Q. Okay. And what you say about it is,	9	do. I think I've read this thing.
10	"Table 3 confirms estimates of CFU per cubic	10	BY MR. GOSS:
11	meter to match" is it Gaison or Galson and	11	Q. Okay. And I
12	Goddard?	12	A. A buddy of mine gave it to me.
13		13	· · · · · · · · · · · · · · · · · · ·
14	A. No, it's Galson. It's a typo.Q. Okay.	14	Q. Okay. I looked in here and I didn't see it.
15	A. Should be G-A-L.	15	
16	Q. So table 3 confirms estimates of CFU	16	So if you have a copy, I would
17	per cubic meter to match Galson and Goddard as	17	greatly appreciate one. But A. You went into the ASHRAE archives?
18	•	18	
19	cited in figure 7 of this report?	19	Q. You know, I haven't I haven't done
20	A. Yes.	20	that.
21	Q. All right. So let's go to figure 7	21	A. They are very good. I would expect
22	of your report.	22	it's
23	A. All right.Q. And it's a little difficult to read.	23	Q. Okay. I might try that.
24	A. It is.	24	A. 1968 ASHRAE journal. I imagine it's in there.
25	Q. But it's a slide based on	25	Q. But what this figure is based on is
	Q. But it's a slide based on		Q. But what this figure is based on is
	Page 256		Page 257
			1430 207
1	KOENIGSHOFER	1	KOENIGSHOFER
1 2	KOENIGSHOFER Galson and Goddard's, I guess, measurements of	1 2	
	KOENIGSHOFER Galson and Goddard's, I guess, measurements of CFUs		KOENIGSHOFER of various studies that include measurements of
2	Galson and Goddard's, I guess, measurements of	2	KOENIGSHOFER
2 3	Galson and Goddard's, I guess, measurements of CFUs	2	KOENIGSHOFER of various studies that include measurements of outdoor spore levels and typical average or
2 3 4	Galson and Goddard's, I guess, measurements of CFUs A. Yes.	2 3 4	KOENIGSHOFER of various studies that include measurements of outdoor spore levels and typical average or representative indoor levels."
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2 3 4 5 6 7	Galson and Goddard's, I guess, measurements of CFUs A. Yes. Q and an article caused Hospital Air Conditioning and Sepsis Control. A. That's right.	2 3 4 5 6 7	KOENIGSHOFER of various studies that include measurements of outdoor spore levels and typical average or representative indoor levels." A. Okay. Q. "These levels do not necessarily pose a health threat."
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Galson and Goddard's, I guess, measurements of CFUs A. Yes. Q and an article caused Hospital Air Conditioning and Sepsis Control. A. That's right. Q. All right. A. This was real data, real hospitals in Atlanta. Q. Okay. From 1968? A. Yes, sir. Q. Now, if we go to table 3 in Kowalski. This refers are you there? Page 40. Bottom of page 40. A. Oh, okay. Q. All right. This refers to microbial levels in indoor and outdoor air. I don't see a reference to Galson and Goddard, and I don't see any indication that these measurements relate to hospital air, do you? A. I don't see that particular reference here.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	KOENIGSHOFER of various studies that include measurements of outdoor spore levels and typical average or representative indoor levels." A. Okay. Q. "These levels do not necessarily pose a health threat." But I don't see a reference to Galson and Goddard in the references for the bibliography. So what I'm trying to understand is the connection between table 3 of Kowalski '98 and your figure 7. A. All I'm simply saying, within the order of magnitude he's reporting, you know, 50 colony-forming units per cubic meter. Q. Okay. A. And Galson, he's got 10. And they need to make this comparison. One is in cubic meters and one is in cubic feet. Q. Would you say with respect to particles and bacteria, if you're within the same order of magnitude, you're essentially saying it's the difference is

	Page 286		Page 287
1	KOENIGSHOFER	1	KOENIGSHOFER
2	than July 2016?	2	Q. And can you tell from this document
3	A. I haven't.	3	whether this test was performed according to
4	Q. Okay.	4	ASHRAE 52.2?
5	A. But I do have that.	5	A. I I don't know the ASHRAE 52.2
6	Q. Okay.	6	test methodology.
7	A. Again, I'm saying that I that's	7	Q. Okay. Have you ever seen a test
8	again, I read this thing two months ago, three	8	report for a filter that is put through a 52.2
9	months ago. I recall him saying that.	9	test?
10	Q. Number 12 you say that you're	10	A. Well, only in the sense if I'm
11	referring to a filter test by Camfil Farr. And	11	looking to recommend a filter, and I'm looking
12	that's a big filter company; correct?	12	at Camfil's website or American Air Filter's
13	A. Yes, it is.	13	website or whoever, they probably will say that
14	Q. You describe, "Flat filter efficiency	14	they according to 52.2 we did this test and
15	measured at 72 percent at 0.4 micron. MERV 14	15	here's the results.
16	<u>*</u>	16	
17	is 75 to 85 percent at 0.3 to 1 micron. So the filter 3M uses is MERV 13, at best."	17	Q. Okay. We spoke earlier about the particle size ranges the 55.2 tests; correct?
18		18	A. Yes.
19	Did I read that correctly? A. Yes.	19	Q. There's .3 to 1 micron, 1 to
20		20	3 microns, and then 3 to 10 microns; correct?
21	(Thereupon, Exhibit 26 was marked for identification.)	21	A. I believe that's what we said. Yeah.
22	BY MR. GOSS:	22	
23		23	Q. All right. So if you look at this graph below, the units are hard to read, but it
24	Q. Is Exhibit 26 the document that you	24	looks like the highest it goes is about
25	were referring to? A. Yes.	25	.9 microns; correct?
23	A. 168.		.7 inicions, correct:
	Page 288		Dogo 200
	_		Page 289
1	KOENIGSHOFER	1	KOENIGSHOFER
1 2		1 2	
	KOENIGSHOFER		KOENIGSHOFER
2	KOENIGSHOFER A. Yes. Right.	2	KOENIGSHOFER A. I don't know what version of 52 we
2	KOENIGSHOFER A. Yes. Right. Q. So you agree with me that this does	2	KOENIGSHOFER A. I don't know what version of 52 we had at that point. And honestly, I don't know
2 3 4	KOENIGSHOFER A. Yes. Right. Q. So you agree with me that this does not appear to have been conducted according to	2 3 4	KOENIGSHOFER A. I don't know what version of 52 we had at that point. And honestly, I don't know if even 52 had even been published at that
2 3 4 5	KOENIGSHOFER A. Yes. Right. Q. So you agree with me that this does not appear to have been conducted according to 52.2?	2 3 4 5	KOENIGSHOFER A. I don't know what version of 52 we had at that point. And honestly, I don't know if even 52 had even been published at that point.
2 3 4 5	KOENIGSHOFER A. Yes. Right. Q. So you agree with me that this does not appear to have been conducted according to 52.2? MS. ZIMMERMAN: Object to form of the	2 3 4 5 6	KOENIGSHOFER A. I don't know what version of 52 we had at that point. And honestly, I don't know if even 52 had even been published at that point. Q. Okay. So you don't know whether
2 3 4 5 6 7	KOENIGSHOFER A. Yes. Right. Q. So you agree with me that this does not appear to have been conducted according to 52.2? MS. ZIMMERMAN: Object to form of the question. Foundation.	2 3 4 5 6 7	KOENIGSHOFER A. I don't know what version of 52 we had at that point. And honestly, I don't know if even 52 had even been published at that point. Q. Okay. So you don't know whether there was a 52
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Page 290 Page 291 1 1 **KOENIGSHOFER KOENIGSHOFER** 2 2 of the box. And "final" would be after it has 2012 New Classification;" correct? 3 3 A. Uh-huh. Yes. been run. That would be, in my experience, a 4 Q. And then below that it says, "Bair 4 very high number to run a filter to. 5 5 Hugger filter model 505;" correct? Typically when you buy a filter, you 6 A. Yes. 6 buy something from Camfil, and it will say Q. And in the test results, first it 7 "replace at" -- usually like 1.5 inches. I 8 8 indicates the test airflow rate and CFMs and don't recall ever seeing one that would say, 9 9 then the velocity and feet per minute; correct? run it up to 2.5 inches. 10 10 A. Yeah. Q. All right. And then it says, "The 11 Q. So that's 48 CFMs was the flow rate 11 minimum efficiency rating value is MERV 14 at 12 and the velocity was 118 feet per minute? 12 48 CMF;" correct? 13 A. Uh-huh. Yes. 13 A. Uh-huh. Yeah. 14 O. And then it lists an initial 14 O. And then it breaks down the minimum 15 resistance in WG and a final resistance in WG; 15 average efficiency at the three different 16 correct? 16 particle ranges; correct? 17 17 A. Yes. A. Yes. 18 Q. All right. And "WG" stands for water 18 Q. Does this appear to you to be a test 19 gauge; correct? 19 report that's consistent with requirements of 2.0 A. The whole things stands for inches of 20 52.2? 21 21 water gauge, yes. MS. ZIMMERMAN: Object to form. Q. Okay. What is your understanding of 22 22 Foundation. 23 the difference between initial resistance and 23 THE WITNESS: I would guess that it 24 final resistance? 24 matches 52 because they state that it 25 A. Well, "initial" is one brand-new out 25 does. But that is the test of a filter in Page 292 Page 293 1 KOENIGSHOFER 1 **KOENIGSHOFER** 2 2 a laboratory. Ph.D technicians? 3 3 BY MR. GOSS: A. No, I don't know. I'm just making 4 4 Q. Okay. If you'll turn to the second this shit up. 5 page -- by the way, you're -- so you're 5 O. I think I understand. 6 distinguishing between a test of a filter in a 6 A. Hey, you know what, it does. Yes. 7 7 laboratory and a test of a filter in the field, In fact, I do know. 8 8 is that what you're suggesting? Q. Okay. 9 9 A. I've had this only -- for only one or A. That says it right there. 10 two minutes here. But I expect that this is 10 Q. All right. There you go. all they did is to test the filter in their 11 11 A. Dr. Kwak. laboratory in their setup. 12 Q. All right. So you're distinguishing 12 13 13 O. Okay. from that situation and the performance of a 14 A. It was not in a Bair Hugger. 14 filter in the Bair Hugger in the field; 15 15 Q. Right. correct? 16 16 A. So --A. Yes, sir. 17 17 Q. Did you ask --Q. But you yourself did not attempt to 18 A. -- it was in a perfectly beautiful 18 determine the filter efficiency or performance sealed-in device. 19 19 of the filter of a Bair Hugger unit in the 2.0 20 Q. Okay. field: correct? 21 21 A. Perfectly. We've got quarter-inch A. That's correct. 22 stainless steel ends on this thing and 22 Q. So on the second page there are 23 wonderful perfect gaskets installed by a Ph.D 23 different fractional efficiency results listed 24 technician in the laboratory. 24 for the different delta Ps, which is the change 25 25 Q. Do you know that these people are in pressure; correct?

Page 294 Page 295 1 1 **KOENIGSHOFER KOENIGSHOFER** 2 2 about? A. Right. 3 3 Q. And if you look at the initial Q. Yes, sir. 4 resistance of .508 inches those are all the 4 A. .7 to 1.0 size range. 5 5 lowest values that are recorded at the far end Q. That's where it goes to 100 percent; 6 6 of the table; correct? correct? 7 7 A. I'm sorry? A. I thought that was your question. 8 8 Q. Do you follow? Q. No. I'm sorry. 9 9 A. Say that -- well, no, I don't. Say It starts -- it starts at 99.1 and .3 10 10 that again. to .4; correct? 11 11 Q. Okay. Sorry. A. Yes. 12 What I want to compare is the initial 12 Q. All right. And then it increases --13 13 resistance of .508 inches of water. A. Yes. 14 A. Got it. 14 O. -- from there? 15 15 O. And the final resistance of A. Uh-huh. 16 16 2.5 inches of water; correct? Q. All right. Exhibit 28 is a similar 17 17 report on the rectangular filter; correct? A. Okav. 18 Q. All right. And the fractional 18 A. Yes. efficiency at the final resistance begins at 19 19 Q. And this too would appear to be a 20 99.1 and goes up to 100; correct? 20 test report or claims to be a test report per 21 21 A. Yes. 52.2; correct? 22 22 Q. Starting with the .3 to .4 micron A. Yes. That's their statement. 23 23 size range; correct? Q. And it reports a MERV value of 24 A. Yes. 24 MERV 14; correct? 25 25 A. Yes. In the 2.5 column you're talking Page 297 Page 296 1 1 KOENIGSHOFER KOENIGSHOFER 2 2 Q. After you saw this Camfil document in Q. Do you have any reason to disagree 3 3 Exhibit 26, did you ask counsel if there was with his testimony that the filters Pentair or 4 4 other efficiency testing that they could Porous supplied to 3M or Arizant would be 5 5 provide you on the Bair Hugger filters? capable of removing bacteria? 6 MS. ZIMMERMAN: Object to -- pardon 6 A. Capable of removing bacteria. I'm 7 7 me. Object to form and to the extent it sure that they could remove some bacteria. 8 8 calls for attorney-client -- pardon me --Q. Do you have an opinion as to the --9 9 attorney work product, I'm going to strike that. 10 instruct the witness not to answer. 10 On item 14 you cite a paper by Brandt 11 11 BY MR. GOSS: and Oguz, among others, comparing the efficacy 12 Q. Did you want to see other efficiency 12 of resistive polymer and forced-air warming. 13 13 data if it existed? A. Yes. 14 A. I have wanted to see other tests. 14 Q. And this paper is from 2010; right? 15 15 Q. You reviewed a deposition of A. Yes. 16 Dr. Robert Crowder. Do you recall reading his 16 Q. Have you seen a more recent paper by Oguz comparing the levels of bacteria in the 17 testimony that his understanding was that both 17 18 of the filter medias that Pentair supplied to 18 operating room during procedures performed with 19 3M and Arizant would be capable of removing 19 the Bair Hugger versus a resistive polymer 20 2.0 bacteria? device? 21 MS. ZIMMERMAN: Object to the form of A. No. No. I have not seen that with 2.2 the question. 22 that particle. 23 23 THE WITNESS: It's a wonderful (Thereupon, Exhibit 29 was marked for 24 24 question. And I don't remember the answer identification.) 25 2.5 to that.

	Page 302		Page 303
1	KOENIGSHOFER	1	KOENIGSHOFER
2	A. Cool.	2	conclusion from what Dr. Elghobashi arrived at;
3	(Thereupon, Exhibit 30 was marked for	3	correct?
4	identification.)	4	A. Yes.
5	BY MR. GOSS:	5	Q. On page 21 of your report you talk
6	Q. Exhibit 30 is a letter to the editor	6	about the Bair Hugger filtration; correct?
7	in the Journal of Hospital Infection; correct?	7	A. Yes.
8	A. Yes.	8	Q. You say, "If we assume the air near
9	Q. You do not recall having seen this	9	the floor of an OR is as clean as a standard
10	before?	10	hospital, which meets ASHRAE minimum standards,
11	A. I have not. I have heard of its	11	that is 10 CFU per cubic foot"; correct?
12	existence.	12	A. Yes.
13	Q. All I would ask you about this, since	13	Q. I want to look back at figure 7.
14	you have not had a chance to read it, obviously	14	That 10 CFU per cubic foot is for general
15	you have not attempted to reconcile what	15	hospital areas; correct?
16	Memarzadeh says with what Dr. Elghobashi says;	16	A. Yes. I was specifically saying the
17	correct?	17	air near the floor.
18	A. That is correct.	18	Q. Okay. So
19	Q. If you'd just look at the last	19	MS. ZIMMERMAN: For the record,
20	paragraph of this. It says, "This	20	Counsel, are you talking about his figure
21	investigation validates Moretti's et al's	21	7 in his report?
22		22	MR. GOSS: Yes. Exactly. On
23	conclusion that forced-air warming technology	23	•
24	does not increase the risk of surgical wound infection."	24	page 22. BY MR. GOSS:
25	Obviously that's a different	25	Q. The part that I can read says, 10 CFU
23	Obviously that's a different		Q. The part that I can lead says, 10 CPO
	Page 304		Page 305
1	Page 304 KOENIGSHOFER	1	Page 305 KOENIGSHOFER
1 2	KOENIGSHOFER	1 2	
			KOENIGSHOFER Q. Well, we looked at some other studies
2	KOENIGSHOFER per cubic foot per general hospital areas. For	2	KOENIGSHOFER
2	KOENIGSHOFER per cubic foot per general hospital areas. For general surgery, autopsy, isolation, the	2 3	KOENIGSHOFER Q. Well, we looked at some other studies that provided airborne CFUs and CFUs per cubic
2 3 4	KOENIGSHOFER per cubic foot per general hospital areas. For general surgery, autopsy, isolation, the emergency it says 4 CFU per cubic foot; right? A. Yes.	2 3 4	KOENIGSHOFER Q. Well, we looked at some other studies that provided airborne CFUs and CFUs per cubic meter; correct?
2 3 4 5	KOENIGSHOFER per cubic foot per general hospital areas. For general surgery, autopsy, isolation, the emergency it says 4 CFU per cubic foot; right? A. Yes. Q. But you chose 10 CFU per cubic foot	2 3 4 5	KOENIGSHOFER Q. Well, we looked at some other studies that provided airborne CFUs and CFUs per cubic meter; correct? A. I'm sure we have sometime today, yes.
2 3 4 5	KOENIGSHOFER per cubic foot per general hospital areas. For general surgery, autopsy, isolation, the emergency it says 4 CFU per cubic foot; right? A. Yes.	2 3 4 5 6	KOENIGSHOFER Q. Well, we looked at some other studies that provided airborne CFUs and CFUs per cubic meter; correct? A. I'm sure we have sometime today, yes. Q. Some of them were under 5, some were under 10; correct? I think one of them was 35.
2 3 4 5 6 7	KOENIGSHOFER per cubic foot per general hospital areas. For general surgery, autopsy, isolation, the emergency it says 4 CFU per cubic foot; right? A. Yes. Q. But you chose 10 CFU per cubic foot because you're measuring CFUs near the floor?	2 3 4 5 6 7	KOENIGSHOFER Q. Well, we looked at some other studies that provided airborne CFUs and CFUs per cubic meter; correct? A. I'm sure we have sometime today, yes. Q. Some of them were under 5, some were
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Page 306 Page 307 1 **KOENIGSHOFER KOENIGSHOFER** 2 2 A. Yes. That is what she reports her -particles." 3 3 anyway, yeah. Opinion number 2, "The Bair Hugger 4 Q. And for your hypothetical calculation 4 draws particles off the floor into the unit. you're assuming a level of CFUs in the OR about 5 5 It functions much like a household vacuum 6 10 times that: correct? cleaner." 7 7 A. Yes, sir. What is your basis for that second 8 8 Q. And your calculation is based on an statement? 9 9 assumption that the filter is 90 percent A. Because it sucks particles off the 10 10 effective; is that right? floor. The legs of the Bair Hugger, the one 11 11 that I looked at, the ones that sit on the A. Yes. That is what I had said. 12 Q. Do you intend to revisit your 12 floor, it's actually about a half an inch. So 13 13 calculation now that you have been provided actually my calculation, when I did it, I 14 14 assumed 1 inch. some other data surrounding the Bair Hugger 15 filters? 15 Q. Okay. 16 16 A. With the little rubber feeder on it A. No. Because you have not yet 17 17 supplied me any data for how it works inside a about a half an inch, so that the velocity was 18 18 Bair Hugger. actually even higher. 19 Q. And you haven't conducted any testing 19 Q. So what size particles did you 20 of your own to determine that? 20 measure it sucking up from the surface? 21 21 A. I have not. A. I didn't --22 2.2 Q. Moving on to your summary of opinions MS. ZIMMERMAN: Object to the form of 23 on page 22. Your first opinion, "The Bair 23 the question. 2.4 24 Hugger operating in an OR will create Q. Or did you? 25 25 turbulence at the floor stirring settled A. I did not measure. I've already Page 308 Page 309 1 1 **KOENIGSHOFER** KOENIGSHOFER 2 2 answered that question numerous times. particles --Q. You're saying it functions much like A. I don't know either. 4 Q. -- the particles weren't vacuumed by 4 a household vacuum cleaner. 5 the vacuum; correct? A. Hmm-mmm. 6 6 A. Right. Q. Is that based just on your 7 7 calculation of the velocity? Q. Did you make any attempt to determine 8 whether the Bair Hugger actually functioned A. Yes, it is. 9 9 like a household vacuum cleaner in this case? Q. Have you done any calculations of the 10 10 MS. ZIMMERMAN: Objection to the form velocity required to dislodge a 10-micron 11 11 particle from the surface? of the question. I think it's 12 12 argumentative and it has been asked and A. I have not. 13 13 Q. Have you refinished a piece of answered. 14 14 BY MR. GOSS: furniture? 15 15 Q. You can answer. A. I have. 16 16 A. I've already said I didn't do any Q. I have too. I suspect Genevieve has. 17 17 testing on this. Have you ever sanded a surface and 18 18 Q. Got it. then vacuumed it? 19 19 "The performance of the filter A. Of floors, yes. Yeah. Sure. 20 2.0 assembly is not appropriately or correctly Q. And then in my experience, I have 21 21 wiped that surface after vacuuming it and been documented." I think we've established that 22 surprised to see particles. 2.2 you, before today, hadn't seen all the 23 23 documentation relating to the Bair Hugger A. What size were the particles that 24 were left? 24 filters; correct? 25 25 Q. I don't know. All I know is that the MS. ZIMMERMAN: Object to the form of

Page 310 Page 311 1 1 **KOENIGSHOFER KOENIGSHOFER** 2 2 based on the Camfil document that you reviewed? the question. There are documents he 3 3 still hasn't seen relating to the --A. It is based on the Camfil document THE WITNESS: I mean, this is based 4 that I reviewed. It is based on, especially 5 5 on the exploded view of the one that I the units that have got the flat filter. Flat 6 6 filters are notorious for warping like this. looked at. 7 And lacking better information that I had, it's Q. Okay. What documentation were you 8 8 expecting to see? not unreasonable to assume that at certain 9 A. It says nothing about the type of 9 times that filter might go wonky and you get 10 10 gasket that it has. The thickness of the leakage past it. (indicating) 11 gasket. The adhesiveness of the gasket. If 11 MS. ZIMMERMAN: Just for the record, 12 there is a gasket. 12 the witness is gesturing with a piece of 13 Q. Do you know whether there is a gasket 13 paper to mimic a flexion in a rectangular 14 on the Bair Hugger filter? 14 box. 15 A. I don't know. 15 BY MR. GOSS: 16 Q. Did you ever ask counsel to provide 16 Q. The filter goes out a square and tips 17 you exemplar filters? 17 somehow so that air can leak past it? 18 18 A. No. I've asked if I could buy a Bair MS. ZIMMERMAN: Thank you. 19 Hugger. 19 THE WITNESS: Yes. 20 Q. Okay. 20 Did you get the wonky part? 21 A. But I haven't done it yet. 21 BY MR. GOSS: 22 Q. In your last four opinions on 22 Q. You say, in summary, you believe that 23 page 23, you say number 1, "The filters in the 23 the use of the Bair Hugger will adversely 24 Bair Hugger are less efficient than those used 2.4 affect the air quality in the OR and at the 25 in the HVAC system serving an OR." Is that 25 patient, this will place the patient at Page 312 Page 313 1 1 **KOENIGSHOFER** KOENIGSHOFER 2 2 MR. GOSS: That's all the questions I increased risk of contracting an HAI. Is that your testimony? have. Thank you for your patience. 4 MS. ZIMMERMAN: Should we take a real 4 A. Yes. Yes, it is. 5 Q. Do you have an opinion that the Bair short break? 6 Hugger is capable of causing a surgical site 6 MR. GOSS: Sure. 7 7 infection? Not just increased risk, but THE VIDEOGRAPHER: Off the record at 8 actually causing. 8 6:32 p.m. 9 MS. ZIMMERMAN: Object to form and 9 (Thereupon, a brief recess was taken.) 10 10 THE VIDEOGRAPHER: Back on the record foundation. 11 THE WITNESS: I have no information 11 at 6:40 p.m. 12 that there is direct causality. 12 FURTHER EXAMINATION 13 13 BY MR. GOSS: BY MS. ZIMMERMAN: 14 Q. Would you agree with me that you can 14 Q. All right. Well, Mr. Koenigshofer, 15 put the cleanest air in the world into a room, 15 as you know, I'm Genevieve Zimmerman. And I am 16 but if skin particles are falling off the 16 one of the lawyers who represents the 17 doctors and nurses into the surgical site, 17 plaintiffs in a coordinated case in Minneapolis 18 that's a problem that can't be solved by the 18 called a "multi-district litigation". 19 19 HVAC system? And I'm going to have some questions 2.0 20 MS. ZIMMERMAN: Objection to form. for you today as well. First, I just want to 21 THE WITNESS: Yes. 21 say for the record, I appreciate your patience 22 Q. And that is a problem that exists 22 with this process. I appreciate that it is 23 whether or not you have a Bair Hugger in the 23 presently a quarter to 7:00 p.m. We have been 24 room; correct? 24 going all day in a very hot room, not under 25 A. Yes. 25 ideal conditions.

EXHIBIT DX40

TO DECLARATION OF PETER J. GOSS IN
SUPPORT OF DEFENDANTS' MOTION TO
EXCLUDE PLAINTIFFS' ENGINEERING
EXPERTS

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Major article

Traffic flow in the operating room: An explorative and descriptive study on air quality during orthopedic trauma implant surgery

Annette Erichsen Andersson RN ^{a,b,*}, Ingrid Bergh RN, PhD ^c, Jón Karlsson MD, PhD ^{d,e}, Bengt I. Eriksson MD, PhD ^{d,e}, Kerstin Nilsson RN, PhD ^a

Key Words: Surgical site infection Door opening Air sampling Colony-forming units **Background:** Understanding the protective potential of operating room (OR) ventilation under different conditions is crucial to optimizing the surgical environment. This study investigated the air quality, expressed as colony-forming units (CFU)/m³, during orthopedic trauma surgery in a displacement-ventilated OR; explored how traffic flow and the number of persons present in the OR affects the air contamination rate in the vicinity of surgical wounds; and identified reasons for door openings in the OR. **Methods:** Data collection, consisting of active air sampling and observations, was performed during 30 orthopedic procedures.

Results: In 52 of the 91 air samples collected (57%), the CFU/m³ values exceeded the recommended level of <10 CFU/m³. In addition, the data showed a strongly positive correlation between the total CFU/m³ per operation and total traffic flow per operation (r = 0.74; P = .001; n = 24), after controlling for duration of surgery. A weaker, yet still positive correlation between CFU/m³ and the number of persons present in the OR (r = 0.22; P = .04; n = 82) was also found. Traffic flow, number of persons present, and duration of surgery explained 68% of the variance in total CFU/m³ (P = .001).

Conclusions: Traffic flow has a strong negative impact on the OR environment. The results of this study support interventions aimed at preventing surgical site infections by reducing traffic flow in the OR.

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The prevention of surgical site infection (SSI) after orthopedic implant surgery is a hot topic for politicians, hospital administrators, and clinicians, given the enormous amount of resources these infections consume in terms of extra costs of medications, reoperations, and extended length of hospital stays. ¹⁻⁴ Adding the human perspective, a recent study indicated that afflicted patients suffer deeply, both physically and emotionally, from the consequences of a deep SSI for a prolonged period. ⁵

Author contributions; A.E.A., I.B., B.E., J.K., and K.N. designed the study; A.E. A. performed data collection and coordination; A.E.A. and I.B. analyzed data; and A.E.A., I.B., B.E., J.K., and K.N. wrote the manuscript.

Conflict of interest: None to report.

Strategies to minimize the risk of SSI can be focused on 3 major areas: the patient, the surgical technique, and the surgical environment. Optimizing the patient preoperatively by applying current knowledge about the risks associated with smoking, malnutrition, ongoing infections and wounds, diabetes, and other underlying diseases and conditions compromising immunologic defense systems can improve postoperative outcomes significantly.⁶⁻⁹ Optimizing the surgical technique by not exceeding the estimated 75th percentile of surgery time based on the type of surgical procedure reduces the risk of SSI and also minimizes blood loss, thereby avoiding the need for (allogeneic) blood transfusions and eliminating postoperative hematomas.¹⁰⁻¹⁵

The present study focused on strategies aimed at optimizing the surgical environment, in particular the air quality in the operating room (OR). Enhancing air quality by reducing airborne contamination has been shown to be of great importance, especially in relation to implant surgery. $^{16-18}$ It has been suggested that levels be maintained at <10 CFU/m 3 during implant surgery, and that clinical

^a Institute of Health and Care Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

^bDepartment of Anesthesia, Surgery and Intensive Care, Sahlgrenska University Hospital, Gothenburg, Sweden

^c School of Life Sciences, University of Skövde, Skövde, Sweden

^d Department of Orthopedics, Sahlgrenska University Hospital, Gothenburg, Sweden

^e Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

^{*} Address correspondence to Annette Erichsen Andersson, RN, Department of Anesthesiology/Surgery, Sahlgrenska University Hospital/Östra, Smörslottsgatan 1, SE-416 85 Gothenburg, Sweden.

E-mail address: annette.erichsen@vgregion.se (A.E. Andersson).

benefits can be expected by reducing it to 1 CFU/m³, ¹⁸ given that very low levels of clinically relevant coagulase-negative staphylococci can initiate a device-related infection.¹⁹ A landmark study found a strong linear relationship between the level of bacterial air contamination and the prevalence of deep SSI.²⁰

The most common ventilation systems in use today are turbulent, displacement, and laminar airflow (LAF) systems. Whereas turbulent and displacement ventilation systems differ primarily in the methods used to supply clean air, both are incapable of opposing heat emissions from people and lamps. Both types of systems are sensitive to movement, leading to the formation of local eddies.²¹ The most important source of airborne contamination is related to the dispersal of particles from persons present in the OR and their movements.²²⁻²⁴ Clothing OR staff in scrubs with lower air permeability compared with conventional scrubs can reduce the dispersal of microorganisms by the OR staff, thereby significantly reducing the airborne contamination. ^{23,25,26} An experimental study has indicated that the protective ability of tightly woven clothing systems can deteriorate after repeated washing and sterilization.²⁷ Another study concluded that unnecessary conversation in the OR can contribute to an increased risk of airborne contamination,²⁸ and a pilot study indicated a possible association between high levels of noise during surgery and SSI.²⁹ The impact of OR door openings on air quality has been investigated in several studies,^{30,31} but clinical tests of this have proven difficult. Ritter et al³² found no significant difference in OR airborne bacterial counts between closed doors (mean, 15.2 CFU) and swinging doors (mean, 14.5 CFU). Stocks et al¹³ reached the same conclusion. Only one study to date has reported a correlation between OR door openings and elevated airborne bacterial counts³³; however, that result was based on 69 passive samples (on settle plates) and only 13 active samples (single-stage slit impact) placed outside the surgical wound area. The aims of the present study were to investigate the air quality, expressed as CFU/m³, during orthopedic trauma implant surgery in a displacement ventilated OR; to explore how traffic flow and the number of people present in the OR affect the air contamination rates in the vicinity of the surgical wound; and to identify reasons for door openings in the OR.

METHODS

Setting

The study was performed at a Swedish university hospital that performs approximately 9,000 surgical procedures annually. Data was collected in 3 parallel ORs of equal size (39 m²), each equipped with an upward air-displacement system supplying cool air (2-3°C below room temperature) above the floor in each of the 4 corners of the room. By thermal convection, the air is evacuated via 4 exhaust fans installed in the ceiling. Each OR is supposed to be maintained at positive air pressure by adjusting the inflow rate to exceed the outflow rate; however, the desired difference in pressure between the outer hall and the OR is not specified. Normally the pressure difference is \sim 3 kPa, and an alarm is activated if the pressure falls so that the difference is neutralized. Each OR has only a single entry point, with the door opening inward, leading directly to the outer hall. The OR teams wore conventional cotton/polyester 50/50 mix shirts and trousers, long surgical hoods tucked in, and private shoes and socks. The scrubbed team also wore reinforced disposable sterile gowns, facemasks (RII), and double-sterile gloves. Adherence to this practice was recorded for every operation. During almost half of the operations, at least one of the air inlet supply devices was partially blocked by medical equipment.

Data were collected during 30 consecutively selected fulllength orthopedic trauma operations involving different types of closed-fracture surgery using plates and screws, intramedullary nails, or hemiarthroplasty. Sampling and data collection were done during the daytime and in most of the cases once a week, over a 7-month period from April to November 2010, with the exception of the holiday month of July.

Air sampling method

A Sartorius MD-8 air scanner (Sartorius Mechatronics, Göttingen, Germany) was used to collect airborne microorganisms. Air was sampled at a flow rate of 3 m³/hour (0.83 L/second) in 20-minute periods continuously during the operations. The instrument was placed outside the sterile zone, and a sterilized flexible hose was extended to reach the wound area, with a filter holder attached to the end. The filter holder with a gelatin filter (3 µm pore size; 80 mm diameter) was placed 20-40 cm from the wound. The filters were placed vertically (n = 60), slightly upward (n = 23), slightly downward (n = 17), or horizontally (n = 3). In those cases in which the OR nurse had problems attaching the filter holder close to the wound (n = 13), the holder was placed on the Mayo stand. Data on filter placement was absent in 4 cases. The filter was changed every 20 minutes by the scrub nurse or the assistant and given to the researcher, who immediately placed it on a nonselective Colombia agar base plate with 5% horse blood. Agar plates were incubated at 30°C for 4 days, after which the total aerobic bacterial count was measured. Microbiological results are expressed as CFU/m³. A total of 116 samples were analyzed; 4 samples were accidentally contaminated and thus excluded from the analysis. Filters and plates were handled using strict aseptic technique. To evaluate the technique, filters that had not been used for air sampling were placed on agar plates and incubated in the same way as the used filters; no bacterial growth was detected.

Observational method

Data was collected using a pretested, structured observation form. The following variables were included: date and time, OR, room temperature, type of surgery and fixation method. The period from incision time to wound closure was divided into 20-minute intervals corresponding to the ongoing air sampling. During 119 intervals (each interval corresponding to 20 minutes of air sampling), traffic flow was measured, as well as the reasons for door openings, and the current step in the surgical procedure was recorded. The number of people present in the OR, patient and researcher excluded, was recorded.

Data analysis

Primary analyses showed that CFU/m³ could not be considered a variable with a normal distribution. For this reason, the linear relationship between CFU/m³ per 20-minute interval and traffic flow per 20-minute interval was investigated using Spearman's rho. To investigate the strength and direction of the linear relationship between the total traffic flow per operation and the total CFU per operation, partial correlations were conducted, enabling the removal of duration of surgery as a potentially confounding variable and thereby giving a more accurate description of the relationship between the variables. Investigations of correlations between normally distributed variables (ie, traffic flow, duration of surgery, and number of people present) were performed using Pearson's product-moment correlation coefficient. Significance was defined as P < .05. All tests were 2-tailed. In relation to hierarchical multiple regression analysis, preliminary analyses were conducted to ensure no important violations of the assumptions of normality, linearity, and multicollinearity.

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One-way between-group analysis of variance with post hoc tests found no significant difference in mean CFU counts among the 3 ORs. However, applying the same test on sampling device positioning indicated that these variations can lead to differences in mean CFU/m³ values. The mean difference between vertically placed filters and filters placed on the Mayo stand was significant (P = .01) (Table 1). In 2 operations involving tibia fractures fixed with an intramedullary nail, the sampling filters had been placed vertically on the opposite leg. During surgery, the injured leg was flexed at 90 degrees, thereby partially or completely blocking the sampling filters with the sterile drape during most of the operation. For this reason, further analysis of air quality in the vicinity of the wound area, samples obtained on the Mayo stand and during the 2 operations for tibia fracture were excluded, leaving 92 samples for analysis. Four operational phase were defined: 1, incision phase; 2, dissection phase; 3, implantation phase; and 4, wound closure phase. Content analysis was used on observational data.³⁴

Ethics

The study was approved by the University of Gothenburg's Ethics Committee (157-10). Written and oral information was provided in line with the 4 principal requirements of the Helsinki Declaration (autonomy, beneficence, nonmalfeasance, and justice). Accordingly, informed consent was obtained from all of the OR teams before observations and sampling.

RESULTS

Air sampling was performed during 30 orthopedic operations in a total of 120 air sampling intervals. The distributions of surgical procedures were 73 plates and screws (60.8%), 26 intramedullary nails (21.7%), and 21 hemiarthroplasties (17.5%). The variations in CFU/m³ values were found between operations rather than during operations (P = .001). In 52 of 91 samples, the CFU/m³ values exceeded the recommended level of <10 CFU/m³. In 14 of 24 operations, the mean values exceeded 10 CFU/m³; in 5 of these operations, the mean values exceeded 25 CFU/m³. The highest mean values were 37.5 and 44.3 CFU/m³. Qualitative analysis revealed high activity levels (ie, movements within the OR as well as traffic flow) during these operations, along with other potentially negative variables, such as hair hanging outside the surgical hood, the presence of a sneezing person, and more than 5 people present in the OR. In 5 operations, mean values were <5 CFU/m³, with the lowest values being 1.6 and 2.3 CFU/m³, and notes written during these operations reveal that there was no traffic flow and low activity. Basic results on air quality, expressed as CFU/m³, and related variables are provided in Table 2.

Traffic flow

The relationships between the total traffic flow rate per operation and the total CFU/m³ sampled per operation and between traffic flow rate per 20-minute interval corresponding to 20 minutes of air sampling were investigated. A positive correlation was found between CFU/m³ and traffic flow rates when measured in 20-minute intervals (r = 0.309; P = .003). The data show a strong, positive correlation between the total CFU/m³ per operation and total traffic flow rate per operation (r = 0.74; P = .001; n = 24 operations). Because duration of surgery correlates to the total CFU and traffic flow rates, duration of surgery was controlled for in the analysis.

A total of 529 door openings were recorded. Reasons for OR entries and exits were grouped into categories, as shown in Table 3. No reason could be identified in relation to 93 entries and exits. To

Table 1CFU/m³ values and sampling positions

				95% confidence interval for mea	
Position	n	Mean	SD	Lower bound	Upper bound
40-20 cm from wor	ınd				
Vertically	60	15.8	13.9	12.2	19.4
Downward	17	15.2	10.2	10.0	20.5
Slightly upward	23	13.0	13.4	7.1	18.8
Horizontally	3	8.6	3.7	-0.74	18.0
Mayo stand					
Vertically	13	6.6	4.4	3.9	9.4
Total	116	13.9	12.6	11.6	16.3

n, number of samples.

Table 2 Air quality and related variables

Variables	n (missing)	Mean (SD)	95% CI for mean	Median (range)
CFU/m ³	91 (1)*	15.9 (13.4)	13.1-18.7	13 (0-55)
Total CFU/m³ per operation	24^{\dagger}	60.4 (55.9)	36.8-84	33.5 (7-187)
Number of people	$111 (9)^{\ddagger}$	5.4(1)	5.2-5.6	5 (3-10)
Traffic flow rate	119 (1) [‡]	4.3 (2.9)	3.8-4.8	4 (0-14)
Traffic flow rate per operation	30^{\dagger}	17.4 (13.5)	12.4-22.4	14 (0-67)
Duration of surgery, minutes	29 (1)§	83.5 (39.7)	68.4-98.5	60 (20-200)

^{*}Number of air samples.

exemplify, this could mean that a staff member would enter the OR, take a look around, and then walk out.

Traffic flow rates in relation to the previously mentioned 4 phases of the operation were analyzed by one-way analysis of variance with post hoc tests showing no significant difference in mean traffic flow rate per 20-minute intervals. In addition, no significant differences in mean CFU/m³ values were found among the different phases. No correlation was detected between the number of people present and traffic flow rates in the OR.

Number of people and the effect on air quality

A minor correlation was found between CFU/m³ and the number of people present in the OR (r = 0.22; P = .04; n = 82).

Duration of surgery and type of surgical procedure

No correlation was found between CFU/m³ rates measured in 20-minute intervals and duration of surgery measured in minutes. A positive correlation was found between the total CFU/m³ per operation and duration of surgery (r = 0.62; P = .01; n = 23). No correlation was found between traffic flow rate per 20-minute interval and duration of surgery, but a strong correlation was noted between total traffic flow rate per operation and duration of surgery (r = 0.79; P = .01; n = 23). Differences in mean CFU values in relation to type of surgical procedure are presented in Table 4.

Predictors of CFU

Hierarchical multiple regression was used to assess the ability of traffic flow and number of people present in the OR to predict CFU/m³ levels after controlling for duration of surgery. Duration of surgery was entered in step 1, explaining 36% (adjusted $R^2 = 0.359$)

[†]Number of operations.

[‡]Measured in 20-minute intervals.

[§]From incision time to end of closure in minutes.

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Table 3Reasons for traffic flow

Necessary door openings*	n	Semi-necessary door openings	n	Unnecessary door openings	n
Expert consultations (eg, help needed from senior surgeons, expert nurses, or anesthesiologists)	40	Surgical team members entering after incision or leaving before closure	76	Logistic reasons planning next or other operation	30
Instruments or other material needed	137	Lunch and coffee breaks	108	Social visits No detectable reasons	45 93
Total	177		184		168 529

^{*}The need assessed in relation to patient safety and ongoing procedure.

 Table 4

 Relationships among CFU, surgical procedures, and traffic flow, analysis of variance

	n	Mean	SD	95% CI	P value
Mean CFU/m ³ value in relation to sur	gical	procedu	ıre*		.001
Plates and screws	69	18.7	13.3	15.5-21.9	
Hemiarthroplasty	11	4.73	9.87	1.1-18.6	
Intramedullary nails	11	4.73	3.1	2.6-6.8	
Mean traffic flow rates in relation to					.004
surgical procedure [†]					
Plates and screws	69	4.5	2.7	3.8-5.1	
Hemiarthroplasty	11	2.3	1.4	1.3-3.3	
Intramedullary nails	11	2.2	2.3	0.6-3.77	

^{*}Number of air samplings corresponding to type of surgical procedure.

of the variance in total CFU/m³ per operation. After entering traffic flow and number of people present, the total variance explained by the model as a whole was 68% [F(3,16) = 14.32; P = .001]. The 2 control measurements, traffic flow and number of people, explained an additional 34% (adjusted $R^2 = 0.336$) of the variance in CFU/m³ when controlling for duration of surgery (R^2 change = 0.34; R^2 change (2,16) = 9.91; R^2 change (2,16) = 0.95; R^2 change (2,16) was statistically significant (standardized R^2 = 0.95; R^2 = 0.001).

DISCUSSION

In orthopedic surgery, large-scale efforts and research activities have focused on infection control, mainly in relation to elective primary joint replacement surgery. The findings of the present study show that the recommended limit of >10 CFU/m³ was exceeded in 57% of the samples analyzed. Patients with orthopedic trauma carry an extra burden of preoperative soft tissue and skeletal damage, and have minimal opportunities to be optimized in relation to comorbidities that are known to be major risk factors in this group of patients.³⁶ Adding smoking habits and old age (the latter of which is common in patients with osteoporotic hip fracture), a picture of a highly vulnerable group of patients emerges. Reducing risk factors in the surgical environment clearly would be beneficial for this group of patients. One of the most important findings of the present study is the highly negative impact of traffic flow in the OR on bacterial contamination of the air close to the wound: that is, a high rate of door openings was associated with high rates of CFU/m³ values. This correlation is weaker when analyzing CFU/m³ per 20-minute interval compared with the total CFU/m³ per operation, which may be related to the unorganized manner in which bacterial dispersion reaches the wound area after an OR entry or exit because of turbulent air flow patterns as well as movement of people in the OR. Analysis of the factors affecting traffic flow found that only 7% of the door openings were related to the need for expert consultation. Supply issues represented the largest category (26%); improving preoperative planning and communication between the surgeon and OR nurse in charge could possibly reduce these door openings. Staff breaks accounted for 20% of door openings; surgical team members entering or leaving the OR when the wound was open, for 14%. Reductions in all of these large categories of traffic flow are possible. Door openings for logistic reasons could all be avoided by telephone communication. Door openings related to social visits and for no detectable reasons together accounted for 27% of the traffic flow, possibly reflecting an OR culture that accepts door openings for no special reason. Although it is reasonable to think that an individual who enters an OR always has a good reason for doing so, in those cases we could find no link to the ongoing procedure. Blaming individuals for lack of discipline is not be a fruitful way to address this problem, given that the cause probably extends the individual level. In addition, merely counting exits and entries while failing to analyze the reasons behind traffic flow behavior could lead to misdirected interventions.³⁷

Directing the focus of change at an organizational level, including enhanced knowledge, logistics, and perioperative planning, would give the OR staff the necessary tools to minimize door openings in the OR. This would not only minimize traffic flow, but also likely reduce the duration of wound exposure. Lynch et al³⁸ reported a mean rate of 40 door openings per hour for orthopedic total joint surgery, and Young et al³⁹ reported a mean rate of 19.2 per hour for cardiac surgery, compared with the rate of 12.9/hour in the present study. The traffic flow patterns reported in these 3 studies must be considered in light of the high correlation between door opening rate and elevated CFU levels, representing a major patient safety problem.

The large variation in CFU values among operations in the present study is in line with previous reports. 13,20,33 This supports the perception that CFU/m³ level should not be discussed as an independent variable with a presumed normal distribution in the OR, because it is highly dependent on other variables and can be reduced to almost nondetectable levels under optimal conditions. The importance of the duration of surgery in relation to CFU/m³ levels measured at 20-minute intervals was of minor importance. However, the duration of surgery is of clinical relevance, given that the total CFU level increases with increasing duration of surgery, thereby exposing the wound to an increased total number of CFUs and increasing the risk of SSI. 10,40 In addition, longer duration of surgery was associated with in higher total OR traffic flow rates. In this sample, only very small variations in relation to the number of people present in the OR were observed; as a result, the effect of the number of people present in the OR on CFU level could not be investigated thoroughly. The differences in CFU levels related to type of surgery, with fixation with plates and screws associated with the highest levels, can be explained by the fact that these procedures were associated with 50% more door openings. The fact that in almost half of cases, at least one of the air inlet supply devices was partially blocked by medical equipment might suggest that the staff has poor knowledge of how the ventilation system works and how to deal with the reality of underdimensioned operating rooms. To investigate the consequences of blockage of air inlets, it would be necessary to control for how close the medical

 $^{^\}dagger Number$ of surgical procedures corresponding to traffic flow rate per 20-minute interval.

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equipment was placed in relation to the inlet device and also for how large an area of the inlet supply was blocked. These data were not registered in the present study, precluding analysis of the possible impact on air contamination rates. Given that our regression model explains 34% of the variance of total CFU/m³ per operation, future research should aim at developing a clinically relevant predictive model for estimating bacterial contamination under different environmental and behavioral conditions, taking into account clothing systems and activity levels in the OR.

Methodological considerations

Conducting representative air sampling in the OR in live conditions proved highly challenging, and many methodological and technical issues had to be addressed both before and during the present study. The choices of sampling velocity, time, and culture media were based on recommendations from infection control practitioners performing surveillance sampling on a regular basis. Studies have reported that the viability of microorganisms might be affected by prolonged sampling times and high airflow rates. 41,42 Evaluation of the Sartorius air sampler demonstrated no reduction in the viability of cocci after drawing 2.6 m³ for 20 minutes, but negative effects for Escherichia coli. 43 Various cocci were the main relevant species found in the OR,²⁴ and these bacteria also are the leading cause of infections related to implanted medical devices.⁴⁴ Based on this, we believed that the sampling time was an acceptable compromise between the purpose of the study and the need to avoid being overly intrusive during the procedures. However, we consider the wide variety of sampling positions in this study a limitation, which might have led to underestimation of CFU values. The literature typically reports on the distance from the wound to the sampling device (striving to be as close as possible), sampling velocity, and time; unfortunately, methodological issues are rarely studied or discussed. Further studies addressing the positioning of sampling filters, the angle between filters and air flow, sampling velocity in relation to air flow patterns produced by different ventilation systems, and their impact on outcome data are needed. Standardizing an optimal air sampling method would produce reliable data and facilitate comparisons between studies to provide insight into the protective capacity of different ventilation systems during operations. Upward- displacement ventilation systems have been demonstrated to more effectively remove particles compared with conventional systems. 45,46 An experimental study 47 comparing conventional ventilation and upward-displacement ventilation confirmed that the upward displacement system was more efficient in removing particles < 10 µm, but found no difference between the 2 ventilation systems for particles > 10 μ m. ⁴⁷ More importantly, the bacterial air counts were generally higher in the displacement systems than in conventional systems. Considering this in the present study, it is possible that the displacement system produced higher mean CFU/m³ values than what would have been registered under the same circumstances in a conventionally ventilated OR. However, the present study demonstrates that even in a displacement ventilated OR, very low CFU/m³ levels could be obtained by keeping the doors closed and reducing the number of people present.

Even structured observations can be susceptible to bias. 48 Human perceptual errors can affect the obtained information, as well as behavioral distortions, due to the presence of an observer. Several measures were taken to address potential bias: (1) The observational form was pretested and modified, (2) the observer had no previous connection with the ward under observation, and (3) the observer underwent self-training sessions to maximize accuracy. Concealed observations to reduce reactivity were not feasible and were considered a possible source of distrust between

the observed and the observer. To estimate the effect of the presence of an observer, the traffic flow rates at the beginning of the study period (May) were compared with rates measured after 6 months (November); no statistically significant differences in traffic flow rates were detected.

CONCLUSION

This study has clearly linked elevated airborne bacterial counts in the surgical area to door openings in conventionally ventilated ORs, thereby providing the scientific evidence needed to initiate interventions aimed at preventing SSI by reducing traffic flow in the OR. In addition, analyzing the reasons for door openings seems to be of great importance to the success of any intervention implemented.

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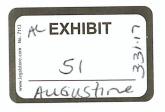
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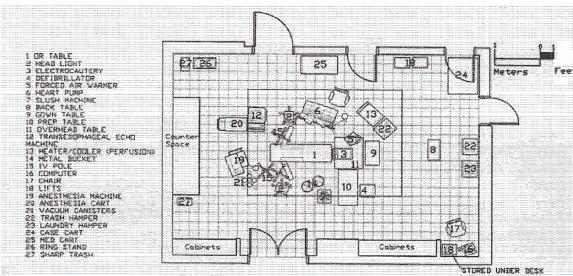
TO DECLARATION OF PETER J. GOSS IN
SUPPORT OF DEFENDANTS' MOTION TO
EXCLUDE PLAINTIFFS' ENGINEERING
EXPERTS





	Equitment	Gives off heat	amount	airflow
1	OR Table	no		
	Head Light	yes		
3	Electrocautery	yes		yes
4	Defibrillator	yes		yes
5	Forced Air Warmer	yes		yes
6	Heat Pump	yes		yes
7	Slush Machine	yes		yes?
8	Back Table	no		
9	Gown	no		
10	Prep Table	no		
11	Overhead Table	no		
12	Transesphageal Echo Machine	yes		yes
13	Heater/cooler (perfusion)	yes		yes
14	Metal Bucket	no		
15	IV Pole	no		
16	Computer	yes		yes
17	Chair	no		
18	Lifts	maybe		
19	Anesthesia Machine	yes		yes
20	Anesthesia Cart	no		
21	Vacuum Canisters	yes		yes
22	Trash Hamper	no		
23	Laundry Hamper	no		
24	Case Cart	no		
25	Med Cart	no		
26	Ring Stand	no		
27	Shamp Trash	no		
	HUMAN FACTOR	YES		yes









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CONFIDENTIAL AUGUSTINES_0000449

EXHIBIT DX42

TO DECLARATION OF PETER J. GOSS IN
SUPPORT OF DEFENDANTS' MOTION TO
EXCLUDE PLAINTIFFS' ENGINEERING
EXPERTS

Temperature Influence in Different Orthopaedic Saw Blades

Søren Toksvig-Larsen, MD, Leif Ryd, MD, and Anders Lindstrand, MD

Abstract: Laboratory tests were carried out on ox bone to evaluate the thermal effect of eight different saw blades while cutting cortical bone. These saw blades represented the usual clinical blades as well as saw blades specially manufactured in an attempt to decrease the temperature. Temperatures between 34°C and 450°C were registered in the saw blades. Only three measurements (of 219 tests) were below 44°–47°C, which is a critical limit for heat-induced bone necrosis. This test indicates that alterating saw blade design is not a way to control the temperature elevation during cutting of bone in orthopaedic procedures. **Key words:** saw blades, bone cutting, temperatures, heat.

Earlier investigations have shown that significant temperature elevations, which cause bone necrosis, may occur when preparing bone with power tools (3, 9, 12, 13, 22, 23). This temperature response could be a factor in the formation of a fibrous tissue membrane and impaired bony ingrowth into porous prostheses (5, 18, 19). It is also conceivable that the heat trauma could have adverse effects on bone healing in general (e.g., delayed healing of osteotomies and ring sequestrum after insertion of pins for external fixation) (14, 16). Attempts to control excessive heat generation in clinical practice by external squirting of saline has been shown to be insufficient during knee surgery (23).

It was our intent to delineate the temperature response while cutting bone with different commercially available saw blades and to investigate whether changes in saw blade design and cutting edge geometry could lower the temperature.

Methods

Temperature measurements were carried out on ox diaphyseal bone. For practical purposes the bone temperatures were about 0°C in most of the tests. Tests with fully thawed bone (18°C–20°C) were done for validation. The bone was cut transversally. Each bone was cut with each saw blade. The size, configuration, and cortical thickness of the different bones used were the same or showed only minor differences

The saw blades tested were the 3M Maxi Driver L122 oscillating, 3M Maxi Driver p512 coarse reciproc, Hall P5002-272 oscillating, and two oscillating blades specially made by Sandvik AB to decrease the temperature generation. These latter blades had chamfer angles (Fig. 1) of 10° and 30° (compared to the ordinary 3M blade chamfer angle of 0°). This should in theory lower the heat energy produced. To evaluate the role of saw blade wear, test series were also made with used 3M Maxi Driver L122 saw blades where teeth were worn, so that one blade had teeth of approximately half the ordinary length and the other was without any real teeth. A saw blade made from two 3M Maxi Driver L122 oscillating saw blades was tested to evaluate the effect of increasing thickness of the blade (Fig. 2).

Exacon CN 7 copper-constantan-type thermocouples (Exacon scientific instruments Aps, Roskilde, Denmark) were embedded in the saw blades, so that the measuring point was within 2 mm of the cutting edge. The thermocouples were connected to a BBC

From the Department of Orthopedics, University Hospital in Lund, S-221 85 Lund, Sweden.

Reprint requests: Søren Toksvig-Larsen, MD, Department of Orthopedics, University Hospital in Lund, S-221 85 Lund, Sweden.

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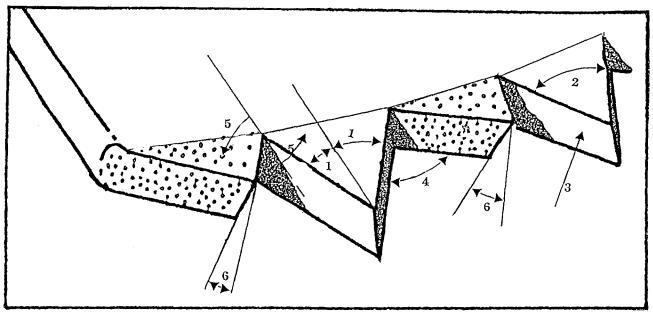


Fig. 1. Saw blade geometry. 1. Rake angle. 2. Wedge angle. 3. Rake plane. 4. Clearance angle. 5. Setting angle. 6. Chamfer angle.

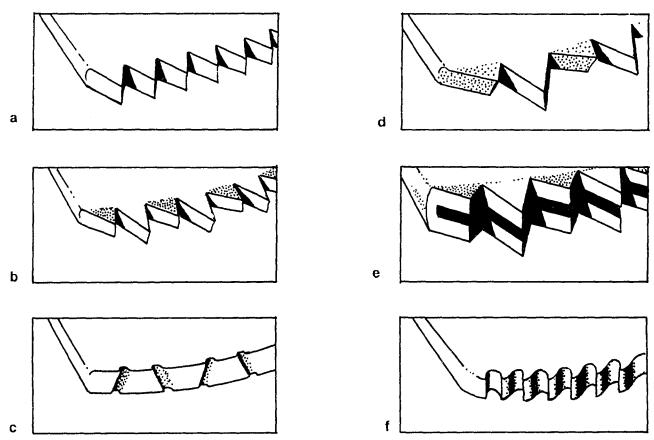


Fig. 2. Saw blade design. (A) 3 M p 512 reciproc. (B) 3 M L122. (C) 3 M L122 modification "half" teeth. (D) 3 M L122 Sandvik modification chamfer angle of 30°. (E) Double saw blade. (F) Hall saw blade.

Table 1. Maximal Temperature of Diaphyseal Ox Bone Cut with Different Saw Blades

	No.	Temperati	are (°C)
Blade	Tests	Average	Range
3M L122	61	101 ± 36	34-184
1/2 teeth	17	196 ± 61	88-290
0 teeth	10	188 ± 110	78-450
Sandvik 10°C	29	93 ± 37	41-194
Sandvik 30°C	18	116 ± 48	53-187
Hall	12	153 ± 38	100-200
3M reciproc	19	103 ± 37	40-200
Double	19	91 ± 19	49-112
Bone 20°C 3M L122	34	108 ± 23	72–171

SE 460 pen recorder (Brown Boveri Goerz Metrawatt, Wien, Austria) having an accuracy of $\pm 1^{\circ}$ C.

An ordinary air-powered 3M Maxi Driver tool (Orthopedic Products Division 3M, St. Paul, MN) connected to the hospital's main air power system was used as the driving equipment. Measured with a stroboscope (Movistrob, Ministrob type 2000) at 6-7 atm pressure, the speed was 15,000-16,000 rpm with the oscillating saw blades and about 3,800 rpm with the reciprocating saw blade. All tests were performed by the same person, who was blinded during the cutting process. All tests were done manually using the speed and pressure used in clinical practice.

The Student's t-test (two tail) was used in statistical methods to compare the results. The number of tests for each blade is given in Table 1.

Results

For the commercial 3M Maxi Driver L122 and 3M reciprocating saw blades and the specially made Sandvik saw blades the median maximal test temperature was between 93°C and 116°C, and there was no statistical difference. The Hall saw blade yielded higher temperatures, with a median maximal temperature of 153°C (P < .001), while the doublethickness saw blade produced a corresponding temperature of 91°C (P > .05). The used saw blades yielded higher temperatures than the new 3M L122 blades, with median maximal temperatures of 196°C and 188° C (P < .001).

When the tests were done on thawed bone (20°C) the median maximal temperature using the 3M Maxi Driver™ L122 saw blade was raised from 101°C to $108^{\circ}C$ (P > .05). Three out of 219 tests resulted in temperatures below 44°-47°C.

The results are shown in Table 1.

Discussion

The problem of heat generation in orthopaedic surgery has been acknowledged previously, especially in the context of curing of cement in joint arthroplasty (6, 7, 10, 11, 15, 17, 20). The temperature while cutting bone has received less attention, although a number of investigators have reported significant temperature elevation (1, 4, 5, 9, 12, 22, 23).

Eriksson (2) has shown that bone tissue is more sensitive to heat than previously postulated. He showed that heating to 44°-47°C in 1 minute severely impaired bone formation.

In clinical bone cutting procedures most chips accumulate because the bone is surrounded by soft tissue and also because the saw teeth tend to push the bone chips into the uncut bone at the front of the teeth. In our studies we had a lesser accumulation of chips because the bone was free from soft tissue. The temperature in the saw blades in our study was approximately 30% higher than the temperature during in vivo bone cutting in knee arthroplasty (69°C) (23) using the same saw equipment. We believe this increase is an overall indication of the differences between the two models (i.e., human metaphyseal bone in vivo versus ox cortical diaphyseal bone in vitro). The temperatures are lower than those reported by Krause et al. (9), who used different tools and test set-up. Tests on thawed bone gave only a small but consistent increase in temperature. In conclusion, we believe that this in vitro test is valid, especially for comparison between different saw blades.

Alteration of the sawing geometry did not lower the temperature significantly below the critical level as shown by the alternate design patterns studied. This is in agreement with Krause et al. (9) who showed that the temperature could only be lowered from 259°C to 170°C by using different rake angles in a laboratory cutting test with reciprocating saws and constant bone feeding. Ludewig (12) did not find any significant differences in the temperature development when he tested three different saw blades in animal experiments.

The chip formation during the machining of bone occurs by a series of discrete fractures (25). A great deal of heat is produced during sawing when the chips are formed and the heat is carried away by the cleaning of the chips. In metal-cutting operations the heat contained in the chips comprises 60 to 70% of the total heat (21). One explanation for the small differences in our series is that the kerf of the saw blades is not cleared, and the chips accumulate and are pushed into the bone at the front of the teeth in a milling process. This may be the reason why the Hall blade yielded higher temperatures. The Hall blade has no offset of the teeth, producing a cut that is exactly as wide as the thickness of the blade. Thus no escape route is provided for the chips, which can only be impacted in the cutting area.

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This investigation showed that there was a rise in temperature with saw wear. Because saw blades in clinical practice are frequently used more than once and in conjunction with a metal template employed as a cutting guide, the potential for blade damage and the production of suboptimal bone surface is high, and a suboptimal cutting process and higher temperatures should be expected. Wevers et al. (24) found that half of the saw blades taken from the operating room were severely damaged. They found that the thrust force was increased when cortical bone was cut with these worn blades. This is in accordance with Matthews and Hirsch (13), who investigated drilling in human cortical femoral bone in vitro and found worn drills to cause much greater temperature changes than new drills, also in accordance with our results.

We did not find any beneficial effects from use of a thick saw blade, in opposition to Klip (8), who, in a small test series, found that the saw blade could not be made too thick. One reason for our findings could be the heat sink phenomenon, which in prosthetic surgery is known to lower the temperature (7).

Orthopaedic surgery involves a great many occasions when bone, after being cut, is expected to heal with another bone surface (e.g., in osteotomies or with prosthetic devices, [i.e., porous, noncemented hip and knee prostheses]). Viable bone is desirable in these instances. It seems reasonable to conclude that alternating saw blade design in the patterns studied here does not appear to be a way to decrease the temperature to less than 44°C. Further development of cutting devices is indicated in order to control the temperature problem.

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EXHIBIT DX43

TO DECLARATION OF PETER J. GOSS IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' ENGINEERING EXPERTS

CASE 0:15 md 02666 INF DTS Doc 910.1 Filed 00/12/17 Dogs 201 of 260



STANDARD

ANSI/ASHRAE Standard 52.2-2017

(Supersedes ANSI/ASHRAE Standard 52.2-2012) Includes ANSI/ASHRAE addenda listed in Appendix H

Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size

See Informative Appendix H for approval dates by the ASHRAE Standards Committee, the ASHRAE Technology Committee, and the American National Standards Institute.

This Standard is under continuous maintenance by a Standing Standard Project Committee (SSPC) for which the Standards Committee has established a documented program for regular publication of addenda or revisions, including procedures for timely, documented, consensus action on requests for change to any part of the Standard. The change submittal form, instructions, and deadlines may be obtained in electronic form from the ASHRAE website (www.ashrae.org) or in paper form from the Senior Manager of Standards. The latest edition of an ASHRAE Standard may be purchased from the ASHRAE website (www.ashrae.org) or from ASHRAE Customer Service, 1791 Tullie Circle, NE, Atlanta, GA 30329-2305. E-mail: orders@ashrae.org. Fax: 678-539-2129. Telephone: 404-636-8400 (worldwide), or toll free 1-800-527-4723 (for orders in US and Canada). For reprint permission, go to www.ashrae.org/permissions.

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NOTE

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FOREWORD

ANSI/ASHRAE Standard 52.2-2017 incorporates addenda to the 2012 edition. The goal of the committee was to improve the end-user experience by standardizing reporting or improving the robustness of the test method to reduce variability. The committee's intentions were to provide the best possible information for the end user to select the best aircleaning devices to protect people and equipment.

Historically, standards for testing air cleaners have been developed in response to the needs of the times. Protection of machinery and coils came first, then reduction of soiling. Now concerns about indoor air quality and respirable particles, protection of products during manufacturing, and protection of HVAC equipment have prompted development of this test standard based on particle size.

Standards Project Committee (SPC) 52.2 was first organized in 1987 to develop a particle size test procedure but was disbanded in 1990 after it became evident that basic research was needed. In 1991, a research contract (ASHRAE Research Project 671, Informative Appendix A, Reference A2) was awarded to review test methodology and recommend approaches for obtaining particle size efficiency data. After the research project was completed and accepted in 1993, SPC 52.2 was reactivated with members representing a broad range of interests. The standard was then formally published in 1999. Changes to the method have been made over the years to improve it and to make it more relevant. The 2017 edition continues that tradition. Appendix H includes a full list of changes by addendum:

- a. Modifications were made to the MERV table to adjust the threshold for specific MERVs and allow for the 16 graduations to be more observable in testing.
- b. To address user concerns about reproducibility and reliability of the test method, ASHRAE commissioned Research Project RP-1088, a comprehensive round robin of multiple labs, including multiple levels of filtration performance. The changes in the 2017 edition of the standard are based on direct recommendations of the research project.
- c. Changes were made with the intent of making the data on reports more mandatory. The goal of the committee was to improve user experience by ensuring that reports being provided by labs and manufacturers would share the same data, allowing for a simpler evaluation of products.
- d. New Informative Appendix K uses the base methodology to test across sequenced filters. This allows users a method of testing their system in a controlled lab environment.

Description of Standard

This standard addresses two air-cleaner performance characteristics of importance to users: the ability of the device to

remove particles from the airstream and its resistance to airflow. Air-cleaner testing is conducted at airflow rates not less than 0.22 m³/s (472 cfm) nor greater than 1.4 m³/s (3000 cfm).

A sample of air from a general ventilation system contains particles with a broad range of sizes having varied effects, sometimes dependent on particle size. Coarse particles, for example, cause energy waste when they cover heat transfer surfaces. Fine particles cause soiling and discoloration of interior surfaces and furnishings as well as possible health effects when inhaled by occupants of the space. When air cleaners are tested and reported for efficiency in accordance with this standard, there is a basis for comparison and selection for specific tasks.

The test procedure uses laboratory-generated KCl particles dispersed into the airstream as the test aerosol. A particle counter measures and counts the particles in 12 size ranges, both upstream and downstream, for the efficiency determinations.

This standard also delineates a method of loading the air cleaner with synthetic dust to simulate field conditions. A set of particle size removal efficiency (PSE) performance curves at incremental dust loading is developed and, together with an initial clean performance curve, is the basis of a composite curve representing the minimum performance in each size range. Points on the composite curve are averaged and the averages are then used to determine the minimum efficiency reporting value (MERV) of the air cleaner.

Coarse air cleaners may be tested for particle size removal efficiency when they are clean, with results reported in the prescribed format. (An example of a coarse air cleaner is the so-called "furnace" filter, a flat panel with a cardboard frame and spun glass fiber media.) However, the standard also provides the basis for evaluation using the loading dust efficiency by weight, or "arrestance," as well as an estimate of predicted life called "dust holding capacity."

Electronic Air Cleaners

Some air cleaners, such as externally powered electrostatic precipitators (also known as electronic air cleaners), may not be compatible with the loading dust used in this test method. The dust contains very conductive carbon that may cause electrical shorting, thus reducing or eliminating the effectiveness of these devices and negatively affecting their MERVs. In actual applications, the efficiency of these devices may decline over time, and their service life is dependent on the conductivity and the amount of dust collected.

Passive Electrostatic Fibrous Media Air Filters

Some fibrous media air filters have electrostatic charges that may be either natural or imposed on the media during manufacturing. Such filters may demonstrate high efficiency when clean and a drop in efficiency during their actual use cycle. The initial conditioning step of the dust-loading procedure described in this standard may affect the efficiency of the filter but not as much as would be observed in actual service. Therefore, the minimum efficiency observed during testing may be higher than that achieved during actual use.

Not an Application Standard

Users should not misinterpret the intent of this standard. This is a test method standard, and its results are to be used to directly compare air cleaners on a standardized basis irrespective of their applications. Results are also used to give the design engineer an easy-to-use basis for specifying an air cleaner. It is entirely possible that an industry organization may use this test method as the basis for an application standard with, for example, different final resistances.

Footnotes are used throughout this standard to provide nonmandatory guidance for the user in addition to the nonmandatory guidance found in the informative appendices. Footnotes are for information only and are not part of the standard.

Acknowledgments

SSPC 52.2 wishes to acknowledge with thanks the contributions of many people outside the voting membership, including European filtration authorities who made suggestions through the committee's international member. We are also indebted to the many media/filter manufacturers and thirdparty companies that have supported the committee by providing access to skilled and informed volunteers.

1. PURPOSE

This standard establishes a test procedure for evaluating the performance of air-cleaning devices as a function of particle size.

2. SCOPE

- 2.1 This standard describes a method of laboratory testing to measure the performance of general ventilation air-cleaning devices.
- 2.2 The method of testing measures the performance of aircleaning devices in removing particles of specific diameters as the devices become loaded by standardized loading dust fed at intervals to simulate accumulation of particles during service life. The standard defines procedures for generating the aerosols required for conducting the test. The standard also provides a method for counting airborne particles of 0.30 to 10 µm in diameter upstream and downstream of the air-cleaning device in order to calculate removal efficiency by particle size.
- 2.3 This standard also establishes performance specifications for the equipment required to conduct the tests, defines methods of calculating and reporting the results obtained from the test data, and establishes a minimum efficiency reporting system that can be applied to air-cleaning devices covered by this standard.

3. DEFINITIONS AND ACRONYMS

3.1 Definitions. Some terms are defined below for the purposes of this standard. When definitions are not provided, common usage shall apply (see Informative Appendix G, Reference 1).

aerosol particle counter (OPC): an instrument that samples, counts, and sizes aerosol particles. While several different technologies exist for aerosol particle counters (e.g., optical,

aerodynamic, electrostatic mobility), only optical aerosol particle counters based on light scattering are used in this standard. Optical aerosol particle counters are often referred to as "OPCs" and, when the particles are sized into a number of sizing channels, are also sometimes referred to as "aerosol spectrometers."

airflow rate: the actual volume of test air passing through the device per unit of time, expressed in m³/s (ft³/min [cfm]), to three significant figures.

arrestance (A): a measure of the ability of an air-cleaning device with efficiencies less than 20% in the size range of 3.0 to $10.0~\mu m$ to remove loading dust from test air. Measurements are made of the weight of loading dust fed and the weight of dust passing the device during each loading step. The difference between the weight of dust fed and the weight of dust passing the device is calculated as the dust captured by the device. Arrestance is then calculated as the percentage of the dust fed that was captured by the device.

average arrestance (A_{avg}): for an air-cleaning device with efficiencies less than 20% in the size range of 3.0 to 10.0 μ m, the average value of the arrestances made on the device during the loading test, weighted by the amounts of dust fed to the device during each incremental dust loading step.

charge neutralizer: a device that brings the charge distribution of the aerosol to a Boltzman charge distribution. This represents the charge distribution of the ambient aerosol.

coefficient of variation (CV): standard deviation of a group of measurements divided by the mean.

correlation ratio data acceptance criteria: criteria used to determine the adequacy of the correlation data, further defined in Section 10.6.2.

correlation ratio (R): the ratio of downstream to upstream particle counts without the test service installed in the test duct. It is determined from the average of at least three samples. This ratio is used to correct for any bias between upstream and downstream sampling and counting systems, and its calculation is described in Section 10.3.

device: throughout this standard the word *device* refers to aircleaning equipment used in general ventilation for the removal of particles—specifically, the air cleaner being tested.

disposable air filters: filters that are designed to operate through a specified performance range and then be discarded and replaced.

dust holding capacity (DHC): the total weight of the synthetic loading dust captured by the air-cleaning device over all of the incremental dust loading steps.

dust increment: the amount of dust fed during a definite part of the loading procedure.

face area: the gross area of the device exposed to airflow. This area is measured in a plane perpendicular to the axis of the test duct or the specified direction of airflow approaching the device. All internal flanges are a part of this area, but items such as mounting hardware and electrical raceways normally mounted out of the airstream are not included. Face area is measured in m² (ft²) to three significant figures.

face velocity: the rate of air movement at the face of the device (airflow rate divided by face area), expressed in m/s (fpm) to three significant figures.

final filter: a filter used to collect the loading dust that has passed through a device during the test procedure.

final resistance: the resistance to airflow of the air-cleaning device at which the test is terminated and results calculated, expressed in Pa (in. of water).

general ventilation: the process of moving air into or about a space or removing it from the space. The source of ventilation air is either air from outside the space, recirculated air, or a combination of these.

initial resistance: the pressure loss of the device operating at a specified airflow rate with no dust load, expressed in Pa (in. of water).

isokinetic sampling: sampling in which the flow in the sampler inlet is moving at the same velocity and direction as the flow being sampled.

loading dust: a compounded synthetic dust used for aircleaner loading. Specifications for this dust are given in Section 6.2.

media: for a fibrous-type air cleaner, media is that part of the device that is the actual dust-removing agent. Webs of spun fiberglass and papers are examples of air-filter media.

media velocity: the rate of air movement through the filter media (airflow rate divided by net effective filtering area). The term is not applicable to plate-type electronic air cleaners. Media velocity is measured in m/s (fpm) to three significant figures.

net effective filtering area: the total area in the device on which dust collects. For devices using fibrous media, it is the net upstream area of the media exposed to airflow, measured in the plane or general surface of the media. Net effective area excludes the area blocked by sealants, flanges, or supports. In electronic air cleaners, it is the total exposed surface of those electrodes available for dust precipitation, including the ionizing section but excluding supports, holes, and insulators. Net effective filtering area is measured in m² (ft²) to three significant figures.

particle size: the polystyrene latex (PSL) light-scattering equivalent size expressed as a diameter in micrometers (μm, 10⁻⁶ m).

penetration: the fraction (percentage) of particles that pass through the air cleaner as described in Section 10.4.

penetration data acceptance criteria: criteria used to determine the adequacy of the penetration data, further defined in Section 10.6.4.

polydisperse: a characteristic of an aerosol for which the width of its number distribution shows a geometric standard deviation of $\delta_g > 1.5$.

rated airflow: the airflow rate in m3/s (cfm) at which the device is tested. In this standard it is specified by the manufacturer in accordance with Section 8.1.

rated final resistance: the operating pressure loss at the airflow rate at which a device should be replaced or renewed, as recommended by the manufacturer, expressed in Pa (in. of water).

reference filters: dry-media-type filters that are carefully measured for resistance and initial efficiency immediately after a test system is qualified. These filters serve as references to ensure that the test system continues to operate as it did when it was qualified. See Section 5.16.1.

release rate: the particles shedding from a filter after a dust load in particles of a given size released per sample volume.

resistance: the loss of static pressure caused by the device operating at a stated airflow rate, expressed in Pa (in. of water) to an accuracy of ±2.5%.

test aerosol: polydisperse solid-phase (i.e., dry) potassium chloride (KCl) particles generated from an aqueous solution, used in this standard to determine the particle size efficiency of the device under test. Generation of the test aerosol is described in Section 5.3.

test rig: the total assembly consisting of the test duct, the aerosol generator, the loading dust feeder, the particle counters and associated accessories, the instrumentation, and the monitoring equipment.

3.2 Acronyms

ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
CV	coefficient of variation
DHC	dust holding capacity
HEPA	high-efficiency particulate air
MERV	minimum efficiency reporting value
OPC	optical particle counter
PSE	particle size removal efficiency
PSL	polystyrene latex, referring to commercially available particles of various specific sizes
SAE	Society of Automotive Engineers
ULPA	ultra-low penetration air

4. TEST APPARATUS

4.1 Mandatory and Discretionary Requirements. Critical dimensions and arrangements of the test apparatus are shown in the figures of this section and in Section 5. All dimensions shown are mandatory unless otherwise indicated. Tolerances are given on each drawing, and either SI or I-P dimensions are acceptable for any element of the system. Units shown are in mm (in.) unless otherwise indicated. The design of equipment not specified, including but not limited to blowers, valves, and external piping, is discretionary, but the equipment must have adequate capacity to meet the requirements of this standard.

4.2 Test Duct

4.2.1 The test duct is defined in Figures 4-1, 4-2, and 4-3 and is primarily of square cross section, 610 × 610 mm (24 × 24 in.). The duct material must be electrically conductive and electrically grounded, have a smooth interior finish, and be sufficiently rigid to maintain its shape at the operating pressures. The inlet filter bank must contain high-efficiency particulate air (HEPA) filters. Increasing the cross section of the

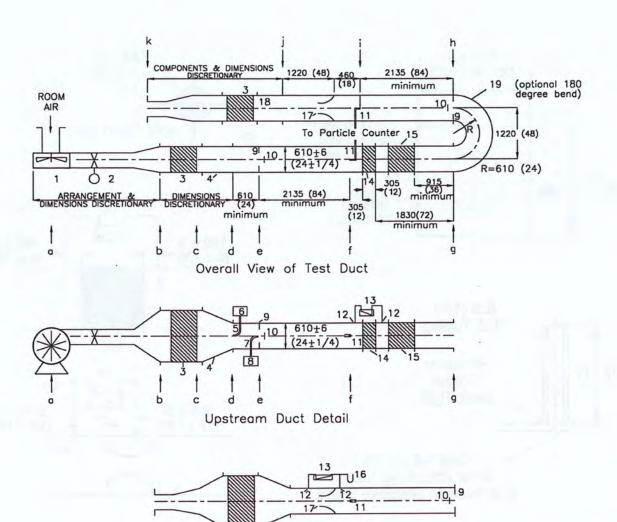


Figure 4-1 Schematic of the test duct (notes and legend are below). Dimensions are in mm (in.).

Notes for Figure 4-1:

1. Duct segments "d" through "j" shall have a cross section of 610 × 610 mm (24 × 24 in.), excluding the device section that has transitions as shown in Figures 4–3a, 4-3b, and 4-3c.

Downstream Duct Detail

- 2. Segments "b" through "g" shall be in centerline alignment.
- 3. Segments "h" through "j" shall be in centerline alignment.
- 4. Upstream airflow and aerosol traverse measurements in accordance with Section 5 shall be performed at "f."
- 5. Aerosol injection shall occur between "c" and "e"; design discretionary in accordance with Section 4.2.4.
- 6. Side-by-side or over-and-under arrangements of the upstream and downstream sections of the test duct are allowed.

LEGEND FOR F	IGURES 4-1 and 4-2d
1. Blower	10. Perforated diffusion plate
2. Flow control valve	11. Location of sample probe
3. HEPA filter bank	12. Static tap
4. Transition, if any, from filter bank to 610 \times 610 mm (24 \times 24 in.) ducting. Maximum transition half angle = 45°.	13. Manometer 14. Air-cleaning device and transitions (if any)
5. Aerosol injection tube	15. Final filter (installed only during dust loading)
6. Aerosol generator	16. Vertical manometer
7. Dust feed pipe	17. Main flow measurement nozzle
8. Dust feeder	18. Transition, if needed
9. Mixing orifice	19. Bend, optional

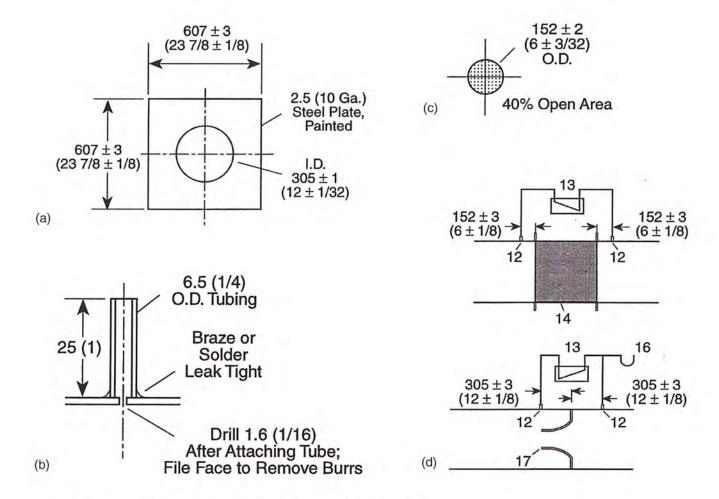


Figure 4-2 Details of test duct components. Dimensions are in mm (in.).

- (a) Mixing orifice.
- (b) Static tap.
- (c) Perforated plate with a sufficient number of equally spaced holes to provide 40% open area.
- (d) Static tap locations.

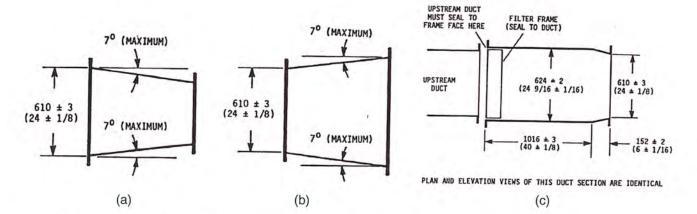


Figure 4-3 Dimensions are in mm (in.).

- (a) Transition: test air-cleaner dimensions smaller than test duct (asymmetrical dimensions are allowed).
- (b) Transition: test air-cleaner dimensions larger than test duct (asymmetrical dimensions are allowed).
- (c) Allowable special duct section for nonrigid air cleaners (must be symmetrical).

- duct at the inlet filter bank to accommodate more than one 610×610 mm (24×24 in.) HEPA filter to minimize pressure drop is allowed. The inlet filter bank must discharge along the centerline of the upstream mixing orifice. System airflow is measured with an American Society of Mechanical Engineers (ASME) flow orifice (Reference 2). The duct must be operated at positive pressure, i.e., the blower discharges into the duct upstream of the test device.
- **4.2.2** The bend (Figure 4-1, #19) in the duct is optional, thereby allowing both a straight duct and a U-shaped duct configuration. Except for the bend itself, all dimensions and components (including the downstream mixing orifice and baffle) are the same for the straight and U-shaped configurations.
- **4.2.3** Room air or recirculated air shall be used as the test air source. The temperature of the air at the test device shall be between 10°C and 38°C (50°F and 100°F) with a relative humidity of $45\% \pm 10\%$ ¹. Exhaust flow shall be discharged outdoors or indoors or recirculated ².
- **4.2.4** An orifice plate and a mixing baffle shall be located downstream of the aerosol injection point. An identical orifice plate/mixing baffle shall be located downstream of the test device 3 . The perforated diffusion plate should be located 152 ± 3 mm ($6 \pm 1/8$ in.) downstream of the mixing orifice and mounted so that the centerline is in line with the hole in the mixing orifice.
- **4.2.5** The test aerosol shall be injected into the duct between the inlet filter bank and the upstream mixing orifice. The aerosol injection system shall produce an upstream challenge that meets the qualification criteria of Section 5.3. The injection system design is discretionary so long as it fulfills this requirement.
- **4.2.6** The test duct shall be isolated from vibration caused by the blower or other sources of vibration.
- **4.2.7** The test apparatus shown in Figure 4-1 is designed for test devices with nominal face dimensions of 610×610 mm (24 × 24 in.). Transitions in accordance with Figures 4-3a and 4-3b shall be used for test devices with face areas from 60% to 150% of the normal test duct cross section area of 0.37 m² (4 ft²). It is permitted to test a bank of several devices if the face area of an individual device is less than 60% of the duct area. It is also permitted to test specially sized air cleaners duplicating the structure of standard units if the size requirement cannot otherwise be met.
- **4.3 Aerosol Generator.** Other than the requirements of the following subsections, design features of the aerosol generator are discretionary. Refer to Informative Appendix B of this standard for guidance.
- A slight temperature increase with a corresponding decrease in relative humidity will occur as the room air passes through the blower.
- HEPA filtration of the exhaust flow is recommended when discharging indoors because test aerosol and loading dust may be present.
- The downstream orifice serves two purposes. It straightens out the flow after going around the bend and it mixes any aerosol that penetrated the test device. Mixing the penetrating aerosol with the airstream is necessary in order to obtain a representative downstream aerosol measurement.

- **4.3.1** The test aerosol shall be polydisperse solid-phase (dry) potassium chloride (KCl) particles generated from an aqueous solution. The aerosol generator shall provide a stable test aerosol of sufficient concentration over the 0.30 to 10 μm diameter size range to meet the requirements of Section 10 without overloading the aerosol particle counter ⁴. Refer to Section 5.6.
- **4.3.2** The aerosol generator shall be designed to ensure that the KCl particles are dry prior to being introduced into the test duct. The relative humidity of the airflow with the particles shall be less than 50%.
- **4.3.3** After drying, the aerosol shall be brought to a Boltzman electrostatic charge distribution by a beta or gamma radiation generator with an activity of at least 185 MBq (5 mCi) or a corona discharge ionizer 5 . The corona discharge ionizer shall have a minimum corona current of 3 μ A and shall be balanced to provide equal amounts of positive and negative ions.
- **4.4 Aerosol Sampling System.** Other than the requirements of the following subsections, the design features of the sampling system are discretionary. Refer to Informative Appendix B of this standard for guidance.
- **4.4.1** The design criterion for the sampling system shall be to provide a particle transport of >50% for 10 μm diameter KCl particles from the sample probe inlet within the test duct to the inlet of the particle counter. This shall be verified by experimental measurement or by numerical calculation of particle transport based on the geometry of the sampling system ⁶, the sampling flow rate, and particle deposition associated with diffusion, sedimentation, turbulent flow, and inertial forces ⁷.
- **4.4.2** The use of a primary and secondary sampling system is allowed to optimize particle transport from the inlet probe to the particle counter ⁸. The primary/secondary sampling system shall meet the following criteria:
- a. The portion of the primary sampling line in the duct shall block less than 10% of the duct cross-sectional area.
- b. Isokinetic sampling (to within 10%) shall be maintained on both primary and secondary probes.
- Air-atomizing spray nozzles in which an aqueous KCl solution is nebulized with compressed air and then dried are a suitable means of aerosol generation.
- Electrostatic charging is an unavoidable consequence of most aerosol generation methods.
- For example, tube diameter, the number of bends, lengths of horizontal and vertical sections.
- A numerical model of aerosol transport has been developed. See Informative Appendix G, Reference 3.
- 8. The primary lines (one from the upstream duct, one from the downstream duct) draw the samples from the duct and transport them to the vicinity of the particle counters. The primary system uses an auxiliary pump and flowmetering system to operate at a higher airflow rate than would be provided by the particle counters alone. The higher airflow rate combined with larger diameter sampling lines improves particle transport. The particle counters then draws a lower flow rate sample from the primary line. The sample lines from the particle counters to the primary sample lines are termed the secondary sample lines.

- c. Flow through the primary sampling system shall be measured to within 5% with volumetric devices (e.g., orifice plates and rotometers).
- d. Combined particle losses in the primary and secondary system shall be <50% for 10 μm diameter KCl particles, based on particle transport modeling.
- The upstream and downstream primary sampling systems shall be of equal length and equivalent geometry.
- The upstream and downstream secondary sampling systems shall be of equal length and equivalent geometry.
- g. The airflow rate of the upstream primary system shall be <2% of the system airflow rate.
- h. The airflow rate of the downstream primary system shall be <2% of the system airflow rate. The extracted airflow rate shall be added to the measured duct airflow rate to obtain the test airflow rate.
- The auxiliary pump and associated flow control and flow measurement devices of the primary sampling lines must be downstream of secondary probes.
- **4.4.3** Diluters, if used, shall provide equal dilution of both the upstream and downstream samples. Dilution of only the upstream samples is disallowed.
- 4.4.4 The upstream and downstream sample lines (both primary and secondary, if used) shall be made of rigid electrically grounded metallic tubing having a smooth inside surface, and they must be rigidly secured to prevent movement during testing. The upstream and downstream sample lines are to be nominally identical in geometry. The use of a short length (50 mm [2 in.] maximum) of straight, flexible, electrically dissipative tubing to make the final connection to the aerosol particle counter is acceptable ⁹.
- **4.4.5** The inlet nozzles of upstream and downstream sample probes shall be sharp edged and of appropriate entrance diameter to maintain isokinetic sampling within 10% at the test airflow rate.
- 4.5 Device Flow Measurement. Flow measurement shall be made by means of ASME long-radius flow nozzles (see Figure 9-1) with static taps as in Figure 4-2b located as shown in Figure 4-2d. The temperature, absolute pressure, and relative humidity of the test airflow shall be measured in the duct immediately upstream of the flow-measuring orifice. These values shall be used for calculation of airflow rate.
- **4.6 Particle Counters.** The particle counter specifications consist of the following:
- a. Measurement technology
- b. Size range
- c. Counting efficiency
- d. Resolution of particle size measurement
- e. Number of sizing channels and their boundaries
- f. Degree of monotonic response required
- g. Calibration methods
- h. Sampling flow rate stability
- i. Zero-count specification
- j. Requirements when dual counters are used
- k. Sample flow rate measurement and recording
- This often relieves stress that would be placed on the instrument's inlet.

Table 4-1 Particle Counters Size Range Boundaries

	Size Range Bo	Geometric Mean		
Size Range	Lower Limit, µm	Upper Limit, μm	Particle Size, μm	
1	0.30	0.40	0.35	
2	0.40	0.55	0.47	
3	0.55	0.70	0.62	
4	0.70	1.00	0.84	
5	1.00	1.30	1.14	
6	1.30	1.60	1.44	
7	1.60	2.20	1.88	
8	2.20	3.00	2.57	
9	3.00	4.00	3.46	
10	4.00	5.50	4.69	
11	5.50	7.00	6.20	
12	7.00	10.00	8.37	

- **4.6.1** The aerosol particle counter shall be based on optical particle sizing and counting (i.e., light scattering). These instruments are commonly known as "optical particle counters" and also as "optical aerosol spectrometers."
- 4.6.2 The particle counters shall count and size aerosol particles in the 0.30 to $10 \mu m$ diameter size range.
- 4.6.3 The counting efficiency shall be at least 50% for 0.3 μ m NIST-traceable polystyrene latex (PSL) particles.
- **4.6.4** The sizing resolution of the particle counter shall be $\leq 10\%$ (standard deviation/mean) and shall be measured in accordance with ISO 21501-1, ISO 21501-4, IEST-RP-CC014.1, or equivalent. The resolution shall be measured at a particle size in the range of 0.5 to 0.7 μm .
- **4.6.5** The particle counters shall group measured particles into 12 size ranges. The range boundaries (based on PSL calibration) shall conform to Table 4-1.
- 4.6.6 The particle counter's correlation of measured response 10 to physical particle size shall be monotonic for PSL particles from 0.30 to 10 μ m, such that only one size range shall be indicated for any measured response (i.e., any lack on monotonic response must be such that the associated ambiguity in particle size is contained within one channel of the particle counter).
- **4.6.7** Particle counter calibration shall conform to the following:
- a. The OPC shall be calibrated in accordance with ISO 21501-4.
- The calibration shall be performed with monodisperse NIST-traceable PSL.
- c. The calibration shall include at least one particle diameter in each of the ranges of 0.3 to 0.4 μm, 9 to 11 μm, and 4 other sizes in between.
- 10. Voltage, for example.

- d. The size calibration of the particle counter shall be performed at least annually.
- 4.6.8 The inlet volume flow rate shall not change more than 2% with a 1000 Pa (4.0 in. of water) change in the pressure of the sampled air.
- **4.6.9** The total measured particle count rate shall be less than 10 particles per minute when the particle counter is sampling air with a high-efficiency filter on its intake.
- 4.6.10 Dual particle counters, if used, shall be identical models such that they are closely matched in design and sampling flow rate.
- **4.6.11** The viewed sample flow rate of the particle counter shall be recorded for each data sample.

Informative Note: Some particle counters incorporate measurement of the viewed sample flow rate within the instrument and provide that measurement as part of the data stream associated with each sample. If the particle counter does not provide this output, provisions need to be made to capture this information for each sample (such as adding a mass flowmeter on the outlet stream from the particle counter's sensor). For some particle counters, viewed sample flow rate can be significantly affected by duct pressure, which can change with flow rate; the resistance of the test filter (clean and with dust loading); and test duct setup (such as the diameter of the ASME flow nozzle and pressure drop of the outlet HEPA filter bank). Changes in flow rate through the particle counter sensor will directly change the particle count rate and lead to errors when computing the particle filtration efficiency values. Changes in flow rate may also influence the particle counter calibration.

In some cases, the influence of duct pressure can be significantly reduced by routing the exhaust of the particle counter back to the duct to equalize (or reduce) the differential pressure across the particle counter, by using a mass flow controller downstream of the particle counter's sensor, or by adding a controlled restriction in the exhaust line of the particle counter.

The viewed sample flow rate is that part of the sample stream that passes through the particle counter's sensor. In many particle counters, 100% of the sample flow flows through the sensor; in some counters and/or sampling systems, the viewed sample flow is a fraction of the total sampled flow (to allow isokinetic sampling, reduced residence time in sample line, etc.).

4.7 Test Apparatus for Dust Loading

- **4.7.1** The test apparatus and materials required by the dust loading procedure shall include the following:
- a. Dust feeder
- b. Dust injection tube
- c. Backup filter
- d. Backup filter duct section
- e. Loading dust
- f. Seals for the particle counter sampling probes
- g. Dust feeder venturi calibrator

- **4.7.2** The dust-feed tube leading from the dust feeder to the center of the dust mixing orifice shall discharge along the centerline of the mixing orifice that is located on the centerline of the test duct.
- **4.7.3** The general design of the dust feeder and its critical dimensions shall conform to Figures 4-4 and 4-5. Backflow through the pickup tube from the positive-pressure duct shall be prevented when the feeder is not in use ¹¹.
- **4.7.4** The aspirator venturi dimensions shall be monitored periodically in accordance with Table 5-2 to ensure that the tolerances shown in Figure 4-5 are met ¹².
- 4.7.5 The gage pressure on the air line to the venturi corresponding to an airflow rate out of the dust-feeder pipe of 6.8 ± 0.2 dm³/s (14.5 ± 0.5 cfm) shall be measured periodically in accordance with Table 5-1. The required gage pressure on the ejector tube supply line necessary to provide this airflow at discharge duct pressures of 0, 500, 1000, 1500, 2000, and 2500 Pa (0, 2, 4, 6, 8, and 10 in. of water) above ambient pressure shall be determined using the test device shown in Figure 4-6. The compressed air supply shall be fitted with a filter-dryer system to provide clean, oil-free air with a dew point no higher than 1.7° C (35° F).

5. APPARATUS QUALIFICATION TESTING

5.1 Apparatus qualification tests shall verify quantitatively that the test rig and sampling procedures are capable of providing reliable particle size efficiency measurements. The tests shall be performed in accordance with Table 5-1.

Qualification tests shall be performed for the following:

- a. Air velocity uniformity in the test duct
- b. Aerosol uniformity in the test duct
- c. Downstream mixing of aerosol
- d. Overload tests of the particle counter
- e. 100% efficiency test
- f. Correlation ratio test
- g. Aerosol generator response time
- h. Duct leakage test
- i. Particle counter zero
- i. Particle counter sizing accuracy
- k. Radioactivity of the aerosol neutralizer
- 1. Dust feeder airflow rate
- m. Final filter efficiency
- n. OPC documentation
- o. OPC flow-rate stability test

5.2 Velocity Uniformity in the Test Duct

5.2.1 The uniformity of the challenge air velocity across the duct cross section shall be determined by a nine-point traverse (Figure 5-1) in the 610×610 mm (24 × 24 in.) duct immediately upstream of the device section. The velocity

- 11. This can be achieved by installing a full-port ball valve in the duct feed pipe between the venturi and the test duct.
- 12. The thoroughness of dust dispersion by the feeder is dependent on the characteristics of the compressed air, the geometry of the aspirator assembly, and the rate of airflow through the aspirator. The aspirator venturi is subject to wear from the aspirated dust and will become enlarged with use.

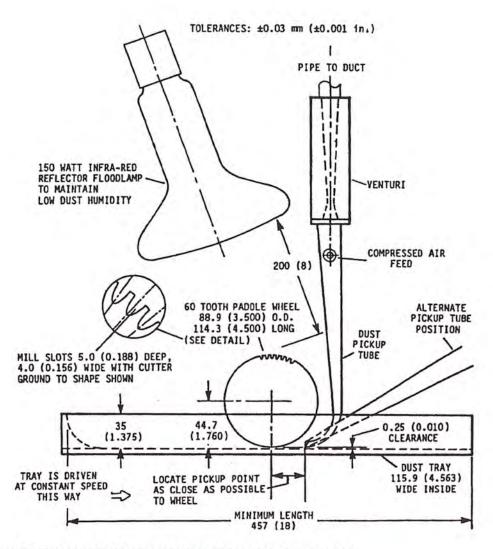


Figure 4-4 Critical dimensions of dust feeder assembly. Dimensions are in mm (in.).

measurements shall be made with an instrument having an accuracy of 10% with 0.05 m/s (approximately 10 fpm) resolution. The uniformity test shall be performed at airflow rates of 0.22, 0.93, and 1.4 m³/s (472, 1970, and 2990 cfm).

- **5.2.2** A one-minute average velocity shall be recorded at each grid point. The average must be based on at least ten readings taken at equal intervals during the one-minute period. The traverse shall then be repeated two more times to provide triplicate one-minute averages at each point for the given airflow rate. The average of the triplicate readings at each point shall be computed.
- **5.2.3** The CV (where CV is the coefficient of variation, computed as the standard deviation/mean) of the nine corresponding grid point air velocity values shall be less than 10% at each airflow rate ¹³.
- 13. If the required degree of velocity uniformity is not achieved, confirm that the blower is providing a constant airflow rate by repeating sampling at the center-of-duct location and confirm that the upstream mixing orifice and baffle are properly centered. Changes may be required to the discretionary ductwork upstream of the upstream mixing orifice.

5.3 Aerosol Concentration Uniformity in the Test Duct

- **5.3.1** The uniformity of the challenge aerosol concentration across the duct cross section shall be determined by a nine-point traverse in the 610×610 mm (24×24 in.) duct immediately upstream of the device section (i.e., at the location of the upstream sample probe) using the grid points as shown in Figure 5-1. The traverse shall be made by either (a) installing nine sample probes of identical curvature, diameter, and inlet nozzle diameter but of variable vertical length or (b) repositioning a single probe. The inlet nozzle of the sample probes shall be sharp-edged and of appropriate entrance diameter to maintain isokinetic sampling within 10% at 0.93 m³/s (1970 cfm). The same inlet nozzle diameter shall be used at all airflow rates.
- 5.3.2 The aerosol concentration measurements shall be made with the particle counter meeting the specifications of Section 4.6. A one-minute sample shall be taken at each grid point with the aerosol generator operating. After sampling all nine points, the traverse shall be repeated four more times to provide a total of five samples from each point. The five values for each point shall then be averaged for each of the 12 particle

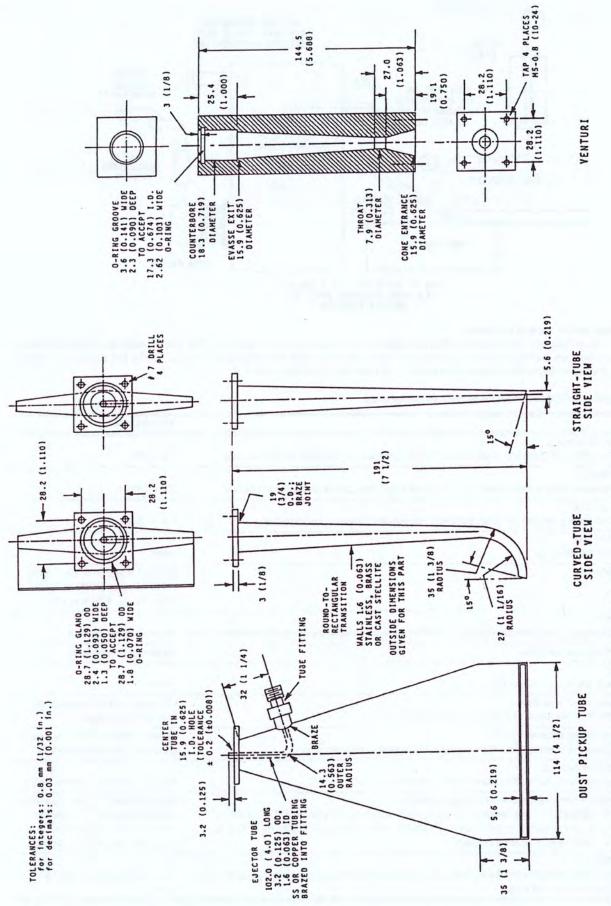


Figure 4-5 Dust feeder ejector/venturi and pickup tube details. Dimensions are in mm (in.).

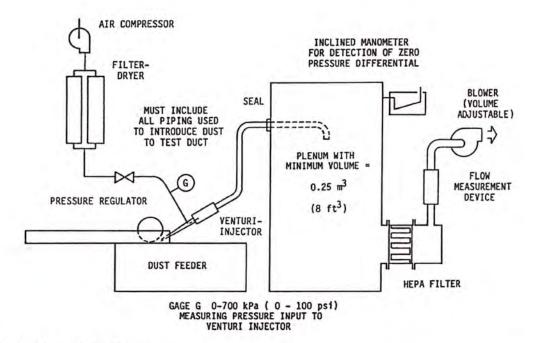


Figure 4-6 Dust feeder venturi calibrator.

Note: Gage G shall measure the pressure of the air supplied to the ejector tube supply line. This venturi calibrator shall be used to determine the pressure reading required to achieve air output from the dust feeder pipe of 6.8 ± 0.2 dm³/s (14.5 ± 0.5 cfm) when there is zero pressure differential between the plenum and ambient. See Section 4.7.5.

Table 5-1 System Qualification Measurement Requirements

Parameter	Requirement
Air velocity uniformity: Based on traverse measurements made over a 9-point equal-area grid at each test airflow rate.	CV < 10%
Aerosol uniformity: Based on traverse measurements made over a 9-point equal-area grid at each test airflow rate.	CV < 15%
Downstream mixing: Based on a 9-point perimeter injection grid and center-of-duct downstream sampling.	CV < 10%
100% efficiency test: Based on HEPA filter test.	>99%
Correlation ratio test	0.30 to 1.0 µm: 0.90% to 1.10% 1.0 to 3.0 µm: 0.80% to 1.20% 3.0 to 10 µm: 0.70% to 1.30%
Upper concentration limit: Based on limiting the concentration to below the level corresponding to the onset of coincidence error.	No predetermined level.
Aerosol generator response time	No predetermined level.
Duct leakage: Ratio of leak rate to test airflow rate.	<1.0%
Particle counter zero count check: Based on HEPA filter attached to the instrument's inlet.	<10 counts per minute over the 0.30 to 10 μm range
Particle counter sizing accuracy check: Based on sampling of aerosolized monodisperse PSL spheres of known size.	Relative maximum must appear in the appropriate sizing channel.
Aerosol neutralizer activity: Based on detection of radioactive source within neutralizer.	Radioactivity must be detected.
Dust feeder airflow rate as a function of discharge pressure: Based on determination of gage pressure on ejector tube supply line to provide $6.8 \pm 0.2 \text{dm}^3/\text{s}$ (14.5 ± 0.5 cfm) for discharge pressures of 0, 500, 1000, 1500, 2000, and 2500 Pa (0, 2, 4, 6, 8, and 10 in. of water) above ambient pressure.	No predetermined gage pressures. Gage pressures are recorded in order to set the proper flow rate during the dust feeder operation.
Final filter efficiency: Based on the difference between the quantity of dust injected and the quantity captured on the final filter with no test device in place.	100 ± 2 g captured for 100 g injected.

Table 5-2 Apparatus Maintenance Schedule

Maintenance Item (Section Reference)	Incorporated Into Each Test	Monthly	Biannually	After Change that May Alter Performance	Comment
Correlation ratio measurement (5.8)	×				
Pressure drop across empty test section (5.16.2)	×				
Background particle count (10.3)	×				
Particle counter zero check (5.10)	×				
Particle counters accuracy check (5.11)	×				
Reference filter check (5.16.1)					Every two weeks
100% efficiency measurement (5.7)		×			
Particle counters primary calibration using PSL					Note 1
Air velocity uniformity (5.2)			×	×	
Aerosol uniformity (5.3)			×	×	
Downstream mixing (5.4)			×	×	
Generator response time (5.5)			×	×	
Overloading test of particle counters (5.6)			×	×	
Duct leak test (5.9)			×	×	
Confirmation of neutralizer radioactivity (5.12)			×	×	Note 5
Dust feeder airflow rate as a function of discharge pressure (5.13)			×	×	
Measurement of venturi dimensions for compliance with Figure 4-5				×	Every 500 hours of operation
Flow rates, pressure drops, temperature, relative humidity, etc.		Note 3			Note 2
Cleaning of test duct and components					Note 4

Notes:

- 1. Calibration performed annually.
- 2. In accordance with manufacturer's recommendations but at least annually.
- 3. Monthly visual inspection for proper installation and operation.
- 4. Cleaning intervals of the test duct, aerosol generator system, aerosol sampling lines, and other test components is discretionary
- 5. Wash the inside of radioactive neutralizer every 100 hours of use. Check balance of the corona discharge ionizer monthly, per manufacturer's instructions.

counter size ranges. The traverse measurements shall be performed at airflow rates of 0.22, 0.93, and $1.4 \text{ m}^3/\text{s}$ (472, 1970, and 2990 cfm).

5.3.3 The CV of the corresponding nine grid point particle concentrations shall be less than 15% for each airflow rate in each of the 12 particle counter size ranges ¹⁴.

5.4 Downstream Mixing of Aerosol

- **5.4.1** A mixing test shall be performed to ensure that all aerosol that penetrates the air cleaner (media or frame) is detectable by the downstream sampler ¹⁵. The mixing test
- 14. If the required degree of aerosol uniformity is not achieved, confirm that the aerosol generator is providing a constant aerosol challenge by repeating sampling at the center-of-duct location. The aerosol injection tube may need to be repositioned and/or additional mixing baffles added to the discretionary ductwork upstream of the upstream mixing orifice.

shall be performed at airflow rates of 0.22, 0.93, and 1.4 m³/s (472, 1970, and 2990 cfm). The point of aerosol injection immediately downstream of the device section shall be traversed and the downstream sampling probe shall remain stationary in its normal center-of-duct sampling location.

5.4.2 A HEPA filter with face dimensions of 610×610 mm (24 × 24 in.) shall be installed to obtain smooth airflow at the outlet of the device section ¹⁶. An aerosol nebulizer shall nebulize a KCl/water solution (prepared using a ratio of 300 g of KCl to 1000 mL water) into an aerosol of primarily submicrometer sizes ¹⁷. A rigid extension tube with a length sufficient to reach each of the injection points shall be affixed to

- 15. For example, when testing a high-efficiency extended surface filter, it is important to know that the downstream probe will detect a leak in a corner of one of the pockets.
- 16. This represents a worst-case condition for aerosol mixing.

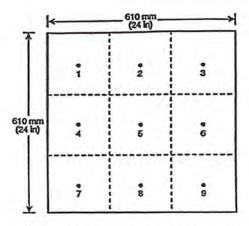


Figure 5-1 Sampling grid with nine equal-area points for measuring the uniformity of air velocity and aerosol dispersion.

the nebulizer outlet. A 90 degree bend shall be placed at the outlet of the tube to allow injection of the aerosol in the direction of the airflow. The injection probe shall point downstream. The aerosol shall be injected immediately downstream (within 250 mm [10 in.]) of the HEPA filter at preselected points located around the perimeter of the test duct and at the center of the duct as indicated in Figure 5-2. The flow rate through the nebulizer and the diameter of the injection tube outlet shall be adjusted to provide an injection air velocity within $\pm 50\%$ of the mean duct velocity.

- **5.4.3 Sampling Sequence.** A one-minute sample from the downstream probe shall be acquired with the nebulizer operating and the injection tube positioned at the first injection grid point. The injection point shall then be moved to the next grid-point location. A new one-minute sample shall be obtained after waiting at least 30 seconds. The procedure shall be repeated until all nine grid points have been sampled.
- **5.4.4** The aerosol injection traverse shall be repeated two more times to provide triplicate measurements at each grid point.
- 5.4.5 The downstream aerosol concentration shall be measured as total aerosol concentration $> 0.30 \mu m^{-18}$. The CV of the corresponding nine downstream grid-point particle concentrations shall be less than 10% for each airflow rate ¹⁹.

5.5 Aerosol Generator Response Time

- **5.5.1** Measure the time interval for the aerosol concentration to go from background level to steady test level ²⁰. The test shall be performed at an airflow rate of 0.93 m³/s (1970 cfm)
- 17. The nebulizer can be of any kind that produces a stable submicrometer aerosol. This nebulizer may be separate from the aerosol generator used to generate the 0.30 to 10 µm challenge aerosol for the efficiency test. A small hand-held nebulizer facilitates the traversing process.
- 18. The combination of (a) evaluating the downstream concentration as the total concentration >0.30 μm and (b) the use of a portable nebulizer greatly simplify and speed up the conduct of the test while maintaining the utility to detect inadequate downstream mixing.

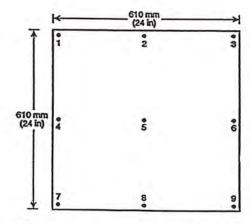


Figure 5-2 Injection grid with nine points to assess downstream mixing. Perimeter points are 25 mm (1 in.) from duct wall.

with the particle counter sampling from the upstream probe. Similarly, measure the time interval for the aerosol to return to background level after turning off the generator.

5.5.2 Measure the time interval for the aerosol concentration to return to the background level after turning off the generator. These time intervals shall be used as the minimum waiting time between (a) activating the aerosol generator and beginning the particle counter sampling sequence and (b) deactivating the aerosol generator and beginning the particle counter sampling sequence for determination of background aerosol concentrations.

5.6 Concentration Limit of the Particle Counter²¹

- 5.6.1 A series of initial efficiency tests shall be performed over a range of challenge aerosol concentrations to determine a total concentration level for the PSE tests that does not overload the particle counters. The lowest total concentration level shall be less than 1% of the instrument's stated total concentration limit. The tests shall be performed following the procedures of Sections 10.1 through 10.6 on a media-type air cleaner using a range of upstream aerosol concentrations. The tests shall be performed at 0.93 m³/s (1970 cfm). The filters selected for this test shall have an initial efficiency in the range of 30% to 70% as measured by the 0.30 to 0.40 μm diameter size range and > 90% efficiency for the 7.0 to 10 μm diameter size range.
- 19. If the required degree of downstream aerosol mixing is not achieved, verify that the downstream mixing orifice and baffle are properly designed and centered. Confirm that the aerosol nebulizer is providing a stable output by injecting the aerosol at the center of the duct location while repeatedly sampling downstream. Improve the stability of the aerosol nebulizer if needed and repeat the downstream mixing test.
- 20. This is to ensure that sufficient time is allowed for the aerosol concentration to stabilize prior to beginning the upstream/downstream sampling sequence during the PSE tests.
- 21. Particle counters may underestimate particle concentrations if the concentration exceeds a certain level. Typically, errors due to overloading result in a lower air-cleaner efficiency due to underestimation of the challenge level because of coincidence error.

- **5.6.2** The aerosol for these tests shall be generated using the same system and procedures as specified in Section 10 for PSE tests.
- 5.6.3 The tests shall be performed over a sufficient range of total challenge concentrations to demonstrate that the particle counters are not overloaded at the intended test concentration ²².

5.7 100% Efficiency Test and Development of Purge Time

- 5.7.1 An initial efficiency test shall be performed using a HEPA or ULPA filter as the test device to ensure that the test duct and sampling system are capable of providing a >99% efficiency measurement. The test procedures for determination of PSE given in Section 10 shall be followed, and the test shall be performed at an airflow rate of 0.93 m³/s (1970 cfm).
- **5.7.2** The computed PSE values shall be greater than 99% for all particle sizes ²³.
- 5.7.3 One parameter affecting the efficiency during the 100% efficiency test is the purge time. The purge time is too short if, after switching from the upstream to the downstream line, residual particles from the upstream sample are counted during the downstream sampling and yield an efficiency of <99%. In this case, the purge time shall be increased and the 100% efficiency test repeated²⁴.

5.8 Correlation Test

- **5.8.1** A test shall be performed without a test device in place to check the adequacy of the overall duct, sampling, measurement, and aerosol generator.
- **5.8.2** The test procedures for determination of the correlation ratio given in Section 10.3 shall be followed ²⁵.
- **5.8.3** The correlation ratio for each particle size shall meet the requirements specified in Table 5-1 ²⁶.

5.9 Test Duct Air Leakage Test

- **5.9.1** Air leakage from the test duct shall not exceed 1% of the total airflow rate.
- 5.9.2 The leak rate of the test duct shall be evaluated by a method similar to that delineated in ANSI/ASME Standard N510 (Reference 4). The test duct shall be sealed immediately upstream of the aerosol injection location and immediately
- 22. The measured filtration efficiencies should be equal over the concentration range where overloading is not significant. The measured filtration efficiency in the 0.30 to 0.40 μm diameter size range will often decrease as the concentration begins to overload the particle counter.
- 23. This test will assess the adequacy of the purge time interval provided between the sequential upstream-downstream concentration measurements. If the purge time is insufficient, residual particles from the relatively high concentration upstream sample will appear in the downstream sample.
- 24. Note that it is not necessary to define the absolute minimum purge time but rather to simply define a purge time that yields acceptable 100% efficiency tests.
- 25. A perfect system will yield correlation ratios of 1 at all particle sizes. Deviations from 1 can occur due to particle losses in the duct, differences in the degree of aerosol uniformity (i.e., mixing) at the upstream and downstream probes, and differences in particle transport efficiency in the upstream and downstream sample lines.

- ately upstream of the exhaust filter bank by bolting a gasketed solid plate to the duct opening or other appropriate means. Carefully meter air into the test duct until the lowest test pressure is achieved. The airflow rate required to maintain the pressure constant shall be measured and recorded as the leak rate, and the test shall then be repeated for the other two test pressures. The measured leak rates shall not exceed 1.0% of the corresponding test airflow rate.
- 5.9.3 To establish the pressure for the leak test, the pressure at the aerosol injection location shall be measured with the duct operating at airflow rates of 0.22, 0.93, and 1.4 m³/s (472, 1970, and 2990 cfm) without a test device installed. To determine the test pressures, add 250 Pa (1 in. of water) to the measured pressures to account for the added resistance of an air cleaner.
- **5.9.4** The highest pressure anticipated by this standard is 3200 Pa (13 in. of water). The user shall exercise caution and shall not pressurize the duct beyond its design limit for personal safety.
- 5.10 Particle Counters Zero. The zero count of the particle counters shall be verified to be <10 total counts per sample time used during testing in the 0.30 to 10 µm size range when operating with a HEPA filter attached directly to the instrument's inlet.
- 5.11 Particle Counters Sizing Accuracy. The sizing accuracy of the particle counters shall be checked by sampling an aerosol containing monodisperse polystyrene spheres of known size ²⁷. A relative maximum particle count shall appear in the particle counter sizing channel that encompasses the PSL diameter.

5.12 Confirmation of the Activity of the Aerosol Neutralizer

- **5.12.1** The activity of the radiation source within the aerosol neutralizer shall be confirmed by use of an appropriate radiation detection device. The measurement may be relative (as opposed to absolute) but shall be adequate to indicate the presence of an active source and shall be capable of being performed in a repeatable manner.
- **5.12.2** The measurement shall be repeated annually and compared to prior measurements to determine if a substantial decrease in activity has occurred. Replace neutralizers showing a lack of activity in accordance with the manufacturer's recommendations ²⁸.
- **5.12.3** The corona discharge level must be high enough to meet the same neutralizing level as from the radioactive source described in Section $4.3.2^{29}$.
- 26. If the correlation ratio falls outside of the required specification at the smaller particle sizes (<1.0 μm), suspect incomplete mixing at the upstream probe location; the aerosol injection tube may need to be realigned or additional mixing provided in the discretionary ductwork upstream of the upstream orifice. If the small particles are within required limits but the larger particles are not, suspect unequal sample line losses. For dual particle-counter systems, also suspect that one of the counters may be out of calibration.</p>
- This is not a calibration but simply a calibration check of the particle counter.
- 28. For example, after one half life.

- **5.13 Dust Feeder Airflow Rate.** Determine and record the gage pressure on the compressed air line to the venturi necessary to provide an airflow rate of 6.8 ± 0.2 dm³/s (14.5 \pm 0.5 cfm) for discharge pressures of 0, 500, 1000, 1500, 2000, and 2500 Pa (0, 2, 4, 6, 8, and 10 in. of water) above ambient pressure 30 .
- **5.14 Final Filter Efficiency.** Weigh the final filter to the nearest 0.1 g and install it in the test duct without the test device installed. The method specified in Section 10.7.3 shall be used to challenge the filter with 100 g of loading dust. Remove and weigh the filter. Its weight increase shall be within 2 g of 100 g.
- **5.15 OPC Documentation.** Secure documentation from the particle counter manufacturer (or other source) that verifies that each specific particle counter requirement of Section 4.6 is being met.

5.16 OPC Flow Rate Stability Check

- 5.16.1 Install a flow restriction (such as an air filter or flow nozzle) in the test section of the test duct that will provide at least a 1000 Pa (4 in. of water) duct pressure difference between the upstream OPC sampling location and the downstream OPC sampling location when the duct is operated at a flow rate between 500 and 2000 cfm.
- **5.16.2** Operate the test duct at a flow rate that yields a $1000 \text{ Pa} \pm 10\%$ (4.0 in. of water $\pm 10\%$) pressure differential between the upstream and downstream OPC sample locations.
- **5.16.3** Measure the sampled flow rate of the OPC when sampling upstream and when sampling downstream. If dual counters are used, measure the flow rate of each OPC.
- 5.16.4 The particle counter's viewed sample flow rate must be the instrument's specified flow rate $\pm 5\%$.
- 5.16.5 The difference between the upstream and downstream viewed sample flow rates must not exceed 2%.

Informative Note to Sections 5.16.4 and 5.16.5: Correct ive action, if needed, may be to route the exhaust of the particle counter back to the duct to equalize the differential pressure across the particle counter; using a mass flow controller downstream of the particle counter's sensor; or adding a controlled restriction in the exhaust line of the particle counter.

- 5.17 Summary of Qualification Test Requirements. Qualification test criteria shall conform to Table 5-1.
- 5.18 Apparatus Maintenance. Maintenance items and schedules shall conform to Table 5-2.

5.18.1 Reference Filter Check

5.18.1.1 For each test duct, a minimum of three identical reference filters shall be maintained by the testing facility solely for initial efficiency testing on a biweekly basis and shall not be exposed to dust loading. The three filters shall be labeled as "primary," "secondary," and "reserve." The primary filter shall be checked every two weeks. If the filtration effi-

- The neutralizing level may be checked using the reference filter test described in Section 5.16.1.
- Gage pressures are used to set the proper flow rate during dust feeder operation.

- ciency values shift by >5 percentage points for any of the 12 particle sizing channels, the secondary filter shall be tested ³¹. If both the primary and secondary filters show shifts >5 percentage points for any of the 12 particle sizing channels, the particle counter shall be recalibrated or other system maintenance performed as needed (e.g., clean sample lines) to restore the reference filter efficiency test to a <5 percentage point shift. The reserve filter shall be used if either the primary or secondary filter becomes unusable (e.g., damaged).
- **5.18.1.2** The measured pressure drop across the reference filter shall be within 10% of the reference value. If the pressure drop deviates by more than 10%, system maintenance shall be performed to restore the pressure drop to within 10% of the reference value ³².
- 5.18.1.3 The reference filter tests shall be performed at $0.93 \text{ m}^3/\text{s}$ (1970 cfm).
- **5.18.1.4** The filtration efficiency of the reference filters shall pass through 50% efficiency in the particle diameter range of 0.7 to 3.0 μ m and be <30% efficiency at 0.30 to 0.40 μ m and >70% efficiency in the 7.0 to 10.0 μ m range ³³.
- **5.18.1.5** Immediately after recalibration of the particle counters, retest each of the reference filters (or a new set of reference filters) to establish new filtration efficiency and pressure drop reference values.
- 5.18.1.6 When either the primary or secondary filter shows shifts >5 percentage points for any of the 12 particle size ranges and the secondary or reserve filter does not, the primary and/or secondary filter shall be replaced with an identical filter or filters, if available, or a new set of identical reference filters shall be obtained ³⁴.
- 5.18.2 Pressure Drop Across Empty Test Section. The pressure drop across the empty test section shall be measured as part of each correlation test performed in accordance with Table 5-2. The measured pressure drop across the empty test section shall be less than 8 Pa (0.03 in. of water); system maintenance shall be performed until the pressure drop is below 8 Pa (0.03 in. of water).

6. TEST MATERIALS

6.1 Test Aerosol. The test aerosol shall be solid-phase potassium chloride (KCl) particles generated from an aqueous solution. The solution shall be prepared by dissolving reagent grade KCl in distilled water ³⁵.

- 31. Percentage points is not to be confused with percent. As an example, the difference between efficiency values of 30% and 35% is 5 percentage points, not 5%.
- 32. Examples of system maintenance steps that can be performed to restore the pressure drop include (but are not limited to) checking for leaks in the ducting and around the flow nozzle and checking the manometer for proper zero and level.
- 33. This is required because detecting shifts in the efficiency curves becomes difficult if the efficiency is either very high or very low for all particle sizes. Changes in the filtration efficiency of electret media reference filters may be due to reduced effectiveness of the neutralizer and its condition should then be checked.
- 34. A reference filter's efficiency may change with the collection of PSE test aerosol after repeated use.

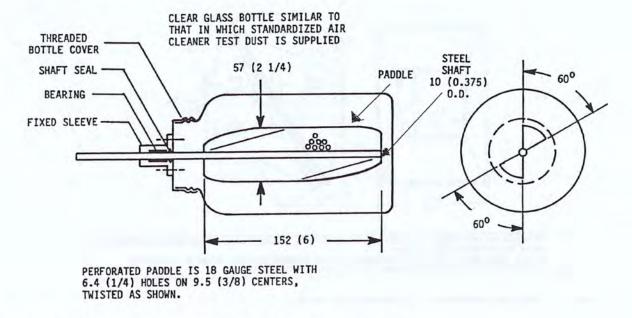


Figure 6-1 Allowable form of a loading dust blender. Dimensions are in mm (in.).

6.2 Loading Dust

- **6.2.1** The loading dust for testing the filtration device shall be composed, by weight, of 72% ISO 12103-1, A2 Fine Test Dust (Reference 5), 23% powdered carbon, and 5% milled cotton linters.
- **6.2.2** The powdered carbon shall be carbon black, with an ASTM D3765 (Reference 6) CTAB surface of $27 \pm 3 \text{ m}^2/\text{g}$, an ASTM D2414 (Reference 7) DBP adsorption of $0.68 \pm 0.7 \text{ cm}^3/\text{g}$, and an ASTM D3265 (Reference 8) tint strength of 43 ± 4 .
- **6.2.3** The cotton linters shall be second-cut linters removed from the cotton seed and ground in a Thomas Wiley Mill or equivalent revolving knife shearing type mill, fitted with a 4 mm screen classifier.
- **6.2.4** A typical 2000 g batch of test dust shall be mixed in a blender until homogeneous, as shown in Figure 6-1, or in a similar blending device as follows:
- a. Dry approximately 1500 g of ISO 12103-1, A2 Fine Test Dust at 104° C (220°F) for 30 minutes. Weigh 1440 ± 1 g of this dust and place in a clean blender.
- b. Dry approximately 600 g of the carbon powder at 104°C (220°F) for 30 minutes. Weigh 460 ± 1 g of this carbon powder and place in the blender. Mix dust and carbon powder for five minutes.
- c. Dry approximately 125 g of milled cotton linters in an oven at 82°C (180°F) for 30 minutes. Weigh 100 ± 1 g of these cotton linters. Sift approximately 20 g through a 14 mesh ASTM E437 (Reference 9) screen into the blender. Mix the dust-carbon powder-linter mixture for two minutes. Repeat the addition and blending of 20 g increments of linters and mixing until all 100 g of the linters and dust-powdered carbon are homogeneously blended.
- 35. A proportion of 300 g KCI to 1 L water is satisfactory.

6.3 Final Filter

- **6.3.1** Capture any test dust that passes through the test device during the dust-loading procedure in a final filter that shall be one of three different forms. In the first form, the filter shall be a flat sheet of filter media, clamped between sealing flanges and backed by a wire screen (see Figure 6-2). In the second form, the filter media shall be inserted in a holding frame in pleats that permit the use of more media than the duct cross section (see Figure 6-3). In the third form, a disposable cartridge filter shall be used (see Figure 6-4).
- **6.3.2** The final filter shall be capable of retaining 98% of the test dust used to load the test device. The design of the final filter and filter media shall be qualified by tests as specified in Section 5.14.

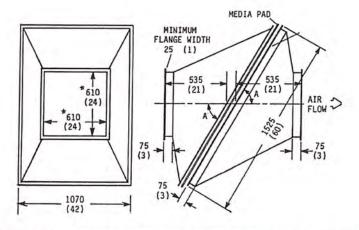
7. SELECTION AND PREPARATION OF THE TEST DEVICE

7.1 Selection Procedures

- **7.1.1** Devices for tests whose results reference this standard shall be selected in accordance with either Section 7.1.3 or Section 7.1.4.
- **7.1.2** These selection procedures shall not apply to developmental testing and the like when results are for in-house use only and not for external presentations.
- **7.1.3** The test sample shall be selected from a group of six or more like air cleaners taken from the manufacturer's assembly line or warehouse.
- **7.1.4** The test sample shall be procured on the open market by the testing laboratory.

7.2 Preparation of the Test Sample

7.2.1 The device to be tested shall be prepared in accordance with the manufacturer's recommendations.



- MEDIA PAD AND GRID/FLANGE DIMENSIONS ARE MANDATORY MINIMA, EXCEPT FOR THOSE MARKED WITH ASTERISKS (*), WHERE THE TOLERANCES ARE ±3 (±1/8).
- 2. LONGER AND WIDER PAD LENGTHS ARE PERMISSIBLE. MAXIMUM BACKUP GRID WIRE SPACING IS 51 MM (2 IN.).
- 3. PAD ORIENTATION MAY BE CHANGED; ANGLE "A" MAY RANGE FROM 9° TO 90°.

Figure 6-2 Final filter: flat sheet media form. Dimensions are in mm (in.).

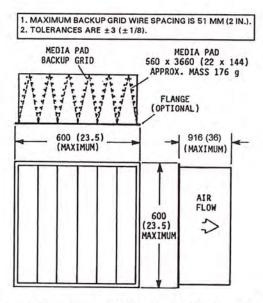


Figure 6-3 Final filter: pleated, replaceable media form. Dimensions are in mm (in.).

- 7.2.2 The device shall be installed in the test duct so that the centerline of the airflow through the device coincides with the centerline of airflow through the duct.
- **7.2.3** Edge leakage and dust accumulation between the device and the test duct shall be minimized by sealing the device and its normal mounting frame to the test section on the upstream side.

8. TEST PROCEDURES

- **8.1 Airflow Rates for Tests.** Tests shall be run and reports generated for an airflow rate as specified in either Section 8.1.1 or Section 8.1.2.
- **8.1.1** Airflow rates for tests conducted for MERV reporting purposes shall be at the upper limit of the test air cleaner's

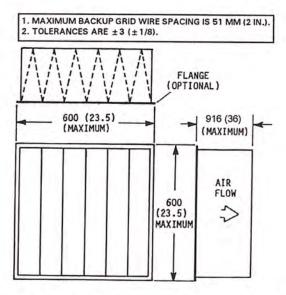


Figure 6-4 Final filter: cartridge form. Dimensions are in mm (in.).

application range. Also, they shall be calculated by first selecting one of the following face velocities in m/s (fpm) and then multiplying by the air cleaner's face area in m² (ft²):

0.60 (118) 2.50 (492) 1.25 (246) 3.20 (630) 1.50 (295) 3.80 (748) 1.90 (374)

- **8.1.2** Test at an airflow rate corresponding to 2.50 m/s (492 fpm) if an air velocity has not been specified.
- **8.1.3** Test to a final resistance of 350 Pa (1.4 in. of water) if a final resistance has not been specified (otherwise test to the specified final resistance) or until the arrestance drops below 85% of the peak value, whichever comes first.
- 8.1.4 Adjust the airflow rate to maintain the selected face velocity when testing devices with other than 610×610 mm

 $(24 \times 24 \text{ in.})$ face dimensions (see Section 4.2.7). Adjusted airflow rate is the product of the selected face velocity and the test device's face area.

8.2 Test Sequence. The sequence of tests on the device shall be as follows:

- Resistance vs. airflow rate of the clean device at various airflow rates as prescribed in Section 9.
- b. PSE of the clean device as prescribed in Section 10.
- PSE of the device when incrementally loaded with synthetic dust as prescribed in Section 10.

9. MEASUREMENT OF RESISTANCE VERSUS AIRFLOW

- 9.1 Install the device in the test duct.
- **9.2** Establish and record airflow rates measured by the flow nozzle. Refer to Figure 9-1. For the purposes of this standard, airflow rate shall be defined by the following equations ³⁶:

$$Q = 1.1107 \times 10^{-6} CD^2 \left\{ \Delta P / [\rho(1 - \beta^4)] \right\}^{0.5}$$
 (SI units)

$$Q = 5.9863 \times CD^{2} \{ \Delta P / (\rho [1 - \beta^{4})] \}^{0.5}$$
 (I-P units)

where

 $Q = \text{test airflow rate, m}^3/\text{s (cfm)}$

 $C = \text{coefficient of discharge} = 0.9975 - 6.53 \text{ Re}^{-0.5}$

D = nozzle throat diameter, mm (in.)

W = duct width, mm (in.)

 $\beta = D/W$

 $\Delta P = \text{nozzle pressure drop, Pa (in. of water)}$

- humid air density at nozzle inlet, kg/m³ (lb/ft³) (Refer to Figure 9-2 or calculate the value in accordance with Section 9 [Reference 11].)
- μ = humid air dynamic viscosity; for the purposes of this standard, it is a constant: 1.817 × 10⁻⁵ N·s/m² (1.22 × 10⁻⁵ lb_m/ft·s)

Re =
$$K \rho Q / \mu D = K_R \rho Q / D$$
, where $K_R = 5.504 \times 10^7 (16,393)$

- 9.3 The pressure drop across the nozzle shall be at least 100 Pa (0.4 in. of water) at the test airflow rate, and the nozzle position and static taps shall conform to Figure 4-1.
- **9.4** Measure and record the resistance of the device at a minimum of four airflow rates: 50%, 75%, 100%, and 125% of test airflow rate. Resistance shall be measured between the static taps.

10. DETERMINATION OF PARTICLE SIZE EFFICIENCY

This section describes the sampling sequence and data analysis procedures for sequential upstream-downstream sampling with one particle counter. For dual particle counter systems with simultaneous upstream-downstream sampling, the same procedures apply except (a) the purge times do not apply and (b) the upstream counts used in the data analysis are the observed, rather than the estimated, values. The data quality

requirements for single and dual particle counter systems are identical.

10.1 Symbols and Subscripts

10.1.1 Symbols

U = upstream counts of each size range (or channel)

D = downstream counts of each size range (or channel)

R = correlation ratio

P = penetration

T = sampling time

 δ_g = standard deviation of a sample

n = number of sample sets

t = t distribution variable

10.1.2 Subscripts

i = sample number

o = observed

c = correlation

b = background

t = testing an air cleaner

u = upstream

d = downstream

e = estimated

lcl = lower confidence limit

ucl = upper confidence limit

n = number of sample sets

pc = particle counter

10.2 Test Sampling

10.2.1 The sampling pattern in Figure 10-1 illustrates one iteration of a sequential upstream-downstream sampling sequence. Sample counts in each size range shall be handled the same way, and this pattern shall be followed for all PSE tests. An initial upstream sample shall be followed by an upstream to downstream purge. Development of purge times is detailed in Section 5.7. The first downstream sampling shall be followed by a downstream to upstream purge and then shall be followed by another upstream sample. The last four time periods shall be repeated for as many sample sets as are required.

10.2.2 The calculations and data quality requirements of Sections 10.3 through 10.7 are performed separately for each of the 12 particle sizing ranges.

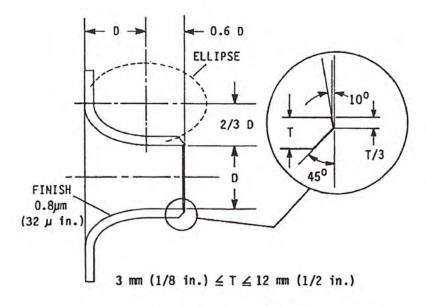
10.3 Correlation Ratio

10.3.1 The correlation ratio (R) shall be used to correct for any bias between the upstream and downstream sampling systems. The correlation ratio shall be established from the ratio of downstream to upstream particle counts without the test device installed in the test duct and before testing an air cleaner and shall be performed at the airflow rate of the aircleaner PSE test. The general equation for the correlation ratio as used in this standard is

 $R = \frac{\text{Downstream particle concentration}}{\text{Upstream particle concentration}}$

with the particle generator on but without a test device in place.

These expressions are derived from ASME Standard MFC-3M-1989 (Informative Appendix G, Reference 10).



D = Nozzle throat diameter, mm (in.)T = Nozzle wall thickness, mm (in.)

Figure 9-1 ASME long-radius flow nozzle dimensions (Reference 6).

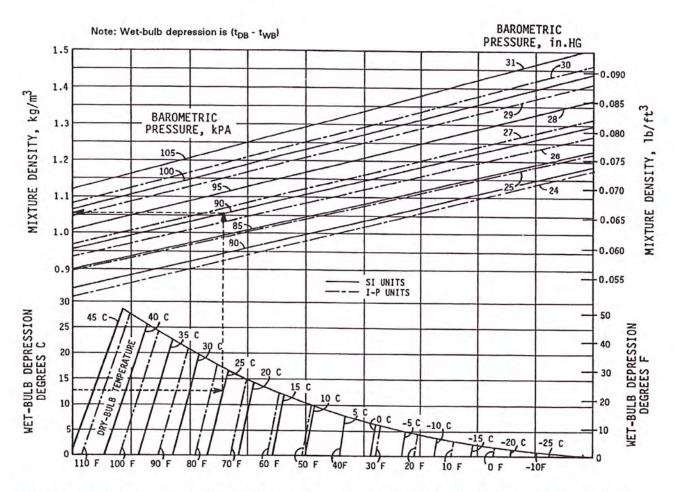


Figure 9-2 Humid air density chart. Barometric pressure as used in this chart is the absolute pressure at the nozzle inlet.

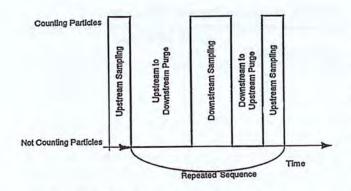


Figure 10-1 Sampling sequences.

- 10.3.2 Background counts shall be made before generating test aerosols. Upstream and downstream sampling shall be done sequentially, starting with an upstream sample $U_{1,o,b}$, followed by a downstream sample $D_{1,o,b}$, alternating back and forth. The total number of samples and sampling times shall be determined by the data quality requirements in Section 10.6.2, except that the final upstream sample is not needed for background sampling. Sampling times upstream and downstream shall be the same for this test.
- 10.3.3 Start generating aerosol when background counts are complete. Begin sampling after stabilization of the test aerosol, starting with an upstream sample $U_{1,o,c}$, followed by a downstream sample $D_{1,o,c}$. An additional upstream sample $U_{(n+1),o,c}$ shall be made following the last downstream sample $D_{n,o,c}$. The total number of samples and sampling times shall be determined by the data quality requirements in Section 10.6.2. Sampling times upstream and downstream shall be the same for this test.
- 10.3.4 Aerosol generation shall be turned off and background sampling shall be repeated after completion of the required correlation sampling sets.
- 10.3.5 The correlation ratio shall then be calculated in accordance with Section 10.6.1.

10.4 Penetration

10.4.1 The device shall be installed in the test section for determination of air-cleaner penetration. For the purposes of this standard, penetration P shall be the fraction of particles that pass through the air cleaner, and the general equation for penetration shall be

$$P = \frac{\text{Downstream particle concentration}}{\text{Upstream particle concentration}}$$

with the particle generator on and the test device in place.

10.4.2 Background counts shall be measured before generating test aerosols. Upstream and downstream sampling shall be done sequentially, starting with an upstream sample $U_{1,o,b}$, followed by a downstream sample $D_{1,o,b}$, alternating back and forth. The total number of samples and sample times shall be determined by the data quality requirements in Section 10.6.4, except that the final upstream sample is not needed for background sampling. A difference between upstream sampling time T_u and downstream sampling time T_d is allowable.

- 10.4.3 Start generating aerosol when background counts are complete. Start sampling with an upstream sample $U_{1,o,t}$, followed by a downstream sample $D_{1,o,t}$, after stabilization of the test aerosol. Take an additional upstream sample $U_{(n+1),o,t}$, following the last downstream sample $D_{n,o,t}$. Sampling times T_u and T_d shall be the same as those used for background sampling.
- 10.4.4 Aerosol generation shall be turned off and background sampling shall be repeated after completion of the required penetration sampling sets.
- 10.4.5 Air-cleaner penetration shall then be calculated in accordance with Section 10.6.3.

10.5 Efficiency

10.5.1 In this standard, the general equation for particle size removal efficiency³⁷ (PSE) shall be

PSE =
$$\left(1 - \frac{\text{Downstream particle concentration}}{\text{Upstream particle concentration}}\right) \times 100$$

= $(1 - \overline{P}) \times 100$

10.5.2 Air-cleaner efficiency shall be calculated in accordance with Section 10.6.5.

10.6 Data Reduction

10.6.1 Correlation Ratio Data Reduction

10.6.1.1 The upstream counts from two samples shall be averaged to obtain an estimate of the upstream counts that would have occurred at the same time as the downstream counts where taken ³⁸.

$$U_{i,e,c} = \frac{U_{i,o,c} + U_{(i+1),o,c}}{2}$$
 (10-1)

10.6.1.2 The background counts before and after the correlation aerosol test generation shall be simply averaged.

$$\overline{U}_b = \frac{\sum_{i=1 \to n} U_{i,o,b}}{n} \tag{10-2}$$

$$\overline{D}_b = \frac{\sum_{i=1 \to n} D_{i, o, b}}{n}$$

10.6.1.3 The correlation ratio shall be calculated for each upstream and downstream sample set using the observed downstream count, the estimated upstream count, the average downstream background count, and the average upstream background count.

$$R_i = \frac{D_{i,o,c} - \overline{D}_b}{U_{i,e,c} - \overline{U}_b}$$
 (10-3)

37. PSE is the fraction of particles that is captured in the air cleaner.38. For example,

$$U_{i,e,c} = \frac{U_{i,o,c} + U_{2,o,c}}{2}, U_{2,e,c} = \frac{U_{2,o,c} + U_{3,o,c}}{2}$$

10.6.1.4 These correlation ratios shall be averaged to determine a final correlation ratio value.

$$\overline{R} = \frac{\sum_{i=1 \to n} R_i}{n} \tag{10-4}$$

10.6.1.5 The standard deviation of the correlation ratio shall be determined by

$$\delta_c = \sqrt{\frac{\sum_{i=1 \to n} (R_i - \overline{R})^2}{n-1}}$$
 (10-5)

10.6.1.6 The standard deviation of the background counts shall be determined by

$$\delta_{u,b} = \sqrt{\frac{\sum_{i=1 \to n} (U_{i,o,b} - \overline{U}_b)^2}{n-1}}$$
 (10-6)

and
$$\delta_{d,b} = \sqrt{\sum_{i=1 \to n} (D_{i,o,b} - \overline{D}_b)^2 \over n-1}$$

10.6.1.7 The 95% confidence limits of the correlation value shall be determined by

$$\overline{R}_{lcl} = \overline{R} - \delta_c \times \frac{t}{\sqrt{n}}$$
 (10-7)

and
$$\overline{R}_{ucl} = \overline{R} + \delta_c \times \frac{t}{\sqrt{n}}$$
 (10-8)

using the t distribution variable from Table 10-1 for a given n.

10.6.1.8 The 95% upper confidence limits of the background counts shall be determined by

$$\overline{U}_{b,ucl} = \overline{U}_b + \delta_{u,b} \times \frac{t}{\sqrt{n}}$$
 (10-9)

and
$$\overline{D}_{b,ucl} = \overline{D}_b + \delta_{u,b} \times \frac{t}{\sqrt{n}}$$
 (10-10)

using the t distribution variable from Table 10-1 for a given n.

10.6.2 Correlation Ratio Data Acceptance Criteria

10.6.2.1 Correlation Ratio Error Limit. The number of correlation sample runs *n* shall be at least three and sufficient to satisfy the following conditions:

$$\delta_c \times \frac{t}{\sqrt{n}} \le 0.05$$
 for particle size ranges 1 through 8 (10-11a)

$$\delta_c \times \frac{t}{\sqrt{n}} \le 0.10$$
 for particle size ranges 9 and 10 (10-11b)

$$\delta_c \times \frac{t}{\sqrt{n}} \le 0.15$$
 for particle size ranges 11 and 12 (10-11c)

This requirement shall be satisfied by calculating this expression after each sample set and halting the testing sequence when the requirement is reached for each size range,

Table 10-1 t Distribution Variable (Reference 12)

Number of Samples, n	Degrees of Freedom, $v = n - 1$	t
3	2	4.303
4	3	3.182
5	4	2.776
6	5	2.571
7	6	2.447
8	7	2.365
9	8	2.306
10	9	2.262
11	10	2.228
12	11	2.201
13	12	2.179
14	13	2.160
15	14	2.145
16	15	2.131
17	16	2.120
18	17	2.110
19	18	2.101
20	19	2.093
21	20	2.086
22	21	2.080
23	22	2.074
24	23	2.069
25	24	2.064
26	25	2.060
27	26	2.056
28	27	2.052
29	28	2.048
30	29	2.045
infinity	infinity	1.960

or by an acceptance criterion for a predetermined number of sample sets.

10.6.2.2 Limits on Magnitude of Correlation Ratio. The correlation ratio shall meet the requirements specified in Table 5-1.

10.6.2.3 Correlation Ratio Maximum Background Counts. The 95% upper confidence limit ³⁹ of the upstream

 This requirement establishes limits on background counts and the required number of background sample sets. and downstream background counts shall be less than 5% of the average estimated upstream count when the particle generation is on.

$$\overline{D}_{b,ucl}, \overline{U}_{b,ucl} < \frac{\sum_{i=1 \to n} U_{i,e,c}}{n \times 20}$$
(10-12)

10.6.2.4 Correlation Ratio Minimum Average Upstream Counts. The sum of the estimated upstream counts shall be greater than or equal to 500. If a sufficient number of counts is not obtained, the sample time or aerosol concentration shall be increased. The aerosol concentration shall not exceed the concentration limit of the particle counters, as determined by Section 5.6.

$$\sum_{i=1 \to n} U_{i, e, c} \ge 500 \tag{10-13}$$

10.6.2.5 Viewed Sample Volume. The particle counter's viewed sample flow rate must be the instrument's specified flow rate $\pm 5\%$.

10.6.3 Penetration Data Reduction

10.6.3.1 The upstream counts from the first two samples shall be averaged to obtain an estimate of the upstream counts that would have occurred at the same time as the downstream counts where taken.

$$U_{i,e,t} = \frac{U_{i,o,t} + U_{(i+1),o,t}}{2}$$
 (10-14)

10.6.3.2 The background counts before and after the penetration test shall be simply averaged.

$$\overline{U}_b = \frac{\sum\limits_{i=1\rightarrow n} U_{i,\,o,\,b}}{n}$$

$$\overline{D}_b = \frac{\sum_{i=1 \to n} D_{i, o, b}}{n} \tag{10-15}$$

where n is the number of background samples taken before and after the penetration test.

10.6.3.3 The observed penetration shall be calculated for each upstream and downstream set using the observed downstream count, the upstream count, the average downstream background count, the average upstream background count, the upstream sampling time, and the downstream sampling time.

$$P_{i,o} = \frac{D_{i,o,t} - \overline{D}_b}{U_{i,e,t} - \overline{U}_b} \times \frac{T_u}{T_d}$$
 (10-16)

10.6.3.4 These observed penetrations shall be averaged to determine an average observed penetration value.

$$\overline{P}_o = \frac{\sum_{i=1 \to n} P_{i,o}}{n}$$
 (10-17)

10.6.3.5 The standard deviation of the observed penetration shall be determined by

$$\delta_{t} = \sqrt{\frac{\sum_{i=1 \to n} (P_{i,o} - \overline{P}_{o})^{2}}{n-1}}$$
 (10-18)

10.6.3.6 The observed penetration shall be corrected by the correlation ratio to yield the final penetration.

$$\overline{P} = \frac{\overline{P}_o}{\overline{R}} \tag{10-19}$$

10.6.3.7 The standard deviation of the correlation ratio shall be combined with the standard deviation of the observed penetration to determine the total error by

$$\delta = \overline{P} \times \sqrt{\left(\frac{\delta_c}{\overline{R}}\right)^2 + \left(\frac{\delta_t}{\overline{P}_o}\right)^2}$$
 (10-20)

10.6.3.8 The 95% confidence limits of the penetration shall be determined by

$$\overline{P}_{lcl} = \overline{P} - \delta \times \frac{t}{\sqrt{n}}$$
 and (10-21)

$$\overline{P}_{ucl} = \overline{P} + \delta \times \frac{t}{\sqrt{n}}$$
 (10-22)

using the t distribution variable from Table 10-1 for a given n.

10.6.3.9 The standard deviation and 95% upper confidence limits for the background counts shall be determined using Equations 10-6, 10-9, and 10-10.

10.6.4 Penetration Data Acceptance Criteria

10.6.4.1 Penetration Error Limit. The number of sample runs n shall be at least three and sufficient to satisfy the following condition:

$$\delta \times \frac{t}{\sqrt{n}} \le 0.07 \times \overline{P} \text{ or } \le 0.05,$$

whichever is greater, for particle size ranges 1 through 8; (10-23a)

$$\delta \times \frac{t}{\sqrt{n}} \le 0.15 \times \overline{P} \text{ or } \le 0.05,$$

whichever is greater, for particle size ranges 9 and 10; (10-23b)

$$\delta \times \frac{t}{\sqrt{n}} \le 0.20 \times \overline{P} \text{ or } \le 0.05,$$

whichever is greater, for particle size ranges 11 and 12. (10-23c)

The requirement shall be satisfied by calculating this expression after each sample set and halting the testing sequence when the requirement is reached for each size range or by an acceptance criteria for a predetermined number of sample sets.

If the above condition cannot be met, the upper confidence limit for penetration (\overline{P}_{ucl}) shall be used to calculate efficiency for that size range.

10.6.4.2 Penetration Maximum Background Counts. For correlation tests and tests before dust loading, the 95% upper confidence limits of the upstream and downstream background counts shall be less than 5% of the average estimated upstream count when the particle generation is ON.

$$\overline{D}_{b, ucl}, \overline{U}_{b, ucl} < \frac{\sum_{i=1 \to n} U_{i, e, t}}{n \times 20}$$
(10-24)

10.6.4.3 Penetration Minimum Upstream Counts. The sum of the estimated upstream counts shall be greater than or equal to 500.

$$\sum_{i=1 \to n} U_{i, e, i} \ge 500 \tag{10-25}$$

10.6.5 Efficiency. Particle size removal efficiency PSE is determined by

$$PSE = (1 - \overline{P}) \times 100$$
 (10-26)

10.7 Test Program for Dust-Loading and Particle Size Efficiency

10.7.1 Test Procedure

10.7.1.1 The test airflow rate shall be selected in accordance with Section 8.1. The final resistance shall be chosen equal to or greater than twice the initial resistance.

10.7.1.2 Particle size efficiency measurements shall be performed at intervals during the dust-loading procedure to establish a curve of efficiency as a function of dust loading. Efficiency curves shall be drawn for any or all of the particle size ranges of the test protocol. Efficiency measurements shall be made at the following points during the dust-loading procedure:

- a. Before any dust is fed to the device.
- b. After an initial conditioning step with a dust loading of 30 g or an increase of 10 Pa (0.04 in. of water) pressure drop across the device, whichever comes first ⁴⁰.
- c. After the dust-loading increments have achieved an airflow resistance increase of one-quarter, one-half, and three-quarters of the difference between the beginning and the prescribed end-point limit of airflow resistance.
- After the dust increment that loads the device to its prescribed end point resistance limit.

10.7.2 Dust-Loading Procedure

10.7.2.1 Weigh the final filter to the nearest 0.1 g.

10.7.2.2 The test duct shall be in the dust-loading configuration with the final filter installed. The dust feeder shall be positioned so that the feeder nozzle is centered in the inlet mixing orifice and the nozzle tip is in the same plane as the orifice. All airflow in the particle sampling lines shall be turned off and their inlets sealed to prevent the entry of loading dust.

40. See Foreword and Informative Appendix A, Section A2.2.

10.7.2.3 Weigh the quantity of dust to ± 0.1 g for one increment of loading.

10.7.2.4 Distribute the dust uniformly in the dust feeder tray. Dust shall be distributed with a depth that will provide a dust concentration in the test of 70 ± 7 mg/m³ (2.0 ± 0.2 g/ 1000 ft³).⁴¹

10.7.2.5 Start the test duct blower and adjust to the test airflow rate for the test device.

10.7.2.6 Turn on the dust feeder heater lamp. Adjust the air pressure regulator on the dust feeder to give the required dust feeder venturi airflow rate, 0.0068 ± 0.0002 m³/s (14.5 ± 0.5 cfm). This condition shall be maintained throughout the feed period. Start the dust feeder tray drive.

10.7.2.7 Maintain the test duct airflow rate at the test flow \pm 2%. After the feeder tray motion is complete, brush dust remaining in the feeder tray into the aspirator. Vibrate or rap the dust feeder tube for 30 seconds.

10.7.2.8 Turn off the feeder tray drive and the airflow to the aspirator venturi. With the test duct airflow on, reentrain any test dust in the duct upstream of the test device by use of a compressed air jet directed obliquely away from the device. Record the airflow resistance of the test device.

10.7.2.9 If several dust increments are required to achieve one quarter of the required flow resistance increase of the device, repeat the steps of Sections 10.7.2.3 through 10.7.2.8. A complete dust increment shall be fed before running the next PSE test.

10.7.2.10 Stop the test duct airflow and remove the final filter from the test duct, taking care to avoid spilling dust from the final filter. Weigh the final filter to the nearest 0.1 g.

10.7.2.11 Collect any test dust deposited in the test duct between the test filter device and the final filter. Weigh the collected dust to the nearest 0.1 g.

10.7.2.12 Add the weight of dust collected in the procedure of Section 10.7.11 to the weight increase of the final filter to establish the amount of synthetic dust passing the device during the feed period.

10.7.2.13 For air-cleaning devices with efficiencies less than 20% in the size range of 3.0 to 10.0 μ m, calculate the arrestance A_i for dust loading increment i as follows:

$$A_i = 100(1 - W_d/W_u) \tag{10-27}$$

where

 A_i = arrestance for dust loading increment i

 W_d = weight of synthetic loading dust passing the device

 W_u = weight of dust fed

10.7.2.14 For all devices, calculate dust holding capacity (DHC) for dust loading increment i as follows:

$$DHC_i = W_u - W_d \tag{10-28}$$

where

 DHC_i = dust holding capacity for dust loading increment

In cases of small dust increments or high airflows, the full length of the feeder tray may not be needed.

 W_d = weight of synthetic loading dust passing the device

 W_u = weight of dust fed

10.7.3 Release Rate

10.7.3.1 Airflow shall be maintained through the device for 20 minutes. Immediately after this 20 minute period, with the airflow on and the aerosol generator OFF, use the aerosol particle counter to collect downstream particle counts over a period of ten minutes. During this time, at least three samples shall be taken. Calculate the 95% upper confidence limits of the background counts for these values using Equation 10-10.

10.7.3.2 The release rate is computed as follows:

Release rate (%) =
$$\frac{D_{b,ucl}}{\sum_{\underline{i}=1-n} U_{i,o,u}} \left(\frac{T_u}{T_d}\right) 100$$
 (10-29)

where the release rate⁴² is expressed in $\#/m^3$, the 95% upper confidence limit is the value calculated in Section 10.7.3.1, and the V_{pc} is equal to the volumetric flow rate of the particle counter, which is multiplied by the sample time of a single count.

- 10.7.3.3 These values shall be reported for each dust increment and size range. If a dilutor is used in sampling, the counts must be corrected by the dilution factor to reflect the actual in-duct undiluted downstream count.
- 10.7.3.4 The efficiency of the air cleaner in a specific size range shall be reported as 0% if during a test run for PSE in that range the PSE is negative.

10.8 Reporting Results of Loading Tests

- 10.8.1 Results of loading tests shall be reported in the form of PSE curves for the test device:
- a. Clean
- After each incremental dust loading, a total of four curves
- At its final loading point
- **10.8.2** Develop a composite minimum efficiency curve by plotting the minimum PSE in each of the 12 size ranges shown on the plots of each of the six curves from Section 10.8.1.
- 10.8.3 The four data points from the Section 10.8.2 composite curve in each of the three size range groups from Table 10-2 shall be averaged and the resultant three average minimum PSEs E_1 , E_2 , and E_3 shall be reported.
- 10.8.4 For air-cleaning devices with efficiencies less than 20% in the size range of 3.0 to 10.0 μ m, calculate the average arrestance A_{avg} as follows:

Table 10-2 Size Range Groups

Average Minimum PSE Designator	Corresponding Size Range Group, μm
E_1	0.30 to 1.0
E_2	1.0 to 3.0
E_3	3.0 to 10

$$A_{avg} = [1/W] \sum_{i=1}^{f} [W_i A_i] (percent)$$
 (10-30)

where

W = total weight of dust fed, g

 W_i = weight of dust fed during loading increment i, g

 A_i = arrestance measured during loading increment i, %

f = final loading increment

10.8.5 For all devices, calculate DHC as

$$DHC = \sum_{i=1}^{f} DHC_i \text{ (grams)}$$
 (10-31)

where

 DHC_i = dust holding capacity for loading increment i

f = final loading increment

10.8.6 Test results shall be reported in accordance with Section 11, and the air cleaner's MERV shall be determined in accordance with Section 12.

11. REPORTING RESULTS

- 11.1 Test results shall be reported using the test report format shown in this standard. Figures 11-1a through 11-1e comprise the complete test report and are examples of acceptable forms. Exact formats are not required, but the report shall include the items shown.
- 11.2 The summary section of the performance report shall include the following information:
- a. Name and location of the test laboratory
- b. Date of the test
- c. Test operator's names
- d. Brand and model number of the particle counting and sizing devices
- e. Air-cleaner manufacturer's name (or name of the marketing organization, if different from the manufacturer)
- f. How the sample was obtained
- g. Description of the test air cleaner, including the following:
 - 1. Brand and model number
 - Physical description of construction (e.g., extended surface—number of pockets or number of pleats; pleated panel—number and depth of pleats)
 - 3. Face dimensions and depth
 - 4. For fiber media air cleaners:
 - i. Type and color of media
 - ii. Effective media area
 - iii. Type and amount of dust adhesive, if known
 - iv. Electrostatic charge, if known
 - 5. Any other pertinent descriptive attributes

^{42.} Optical particle counters are likely to be used to obtain this measure of release rate. Because of the optical properties of the shed dust particles (light absorbing and irregular shape), the sizing of the shed particles as measured by an optical particle counter may be significantly different from their actual physical size. When comparing release rate results, the best comparison will be when the same particle counter is used in all measurements.

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- h. Operating data as stated by the manufacturer
 - Test conditions for reporting purposes: airflow rate and final resistance
 - 2. Initial and final resistances
 - 3. Any other operating data furnished
- i. Test data
 - 1. Test air temperature and relative humidity
 - 2. Airflow rate
 - 3. Type of test aerosol
- j. Results of resistance testing
 - 1. Initial resistance
 - 2. Final resistance
- k. Performance curves
 - A curve in Figure 11-1b format of air-cleaner resistance when clean vs. airflow rates from 50% to 125% of test flow
 - A curve in Figure 11-1c format of PSE for the clean device and for the device at each of the five loading stages
 - A minimum PSE composite curve in Figure 11-1c format whose data points are the lowest PSEs from the six measurements in each particle size range from the curves of test results (Item k[2] above)
 - Resistance vs. synthetic loading dust fed (for aircleaning devices with efficiencies less than 20% in the size range of 3.0 to 10.0 μm)
- Minimum efficiency reporting value (MERV)
 - 1. The average of the minimum PSE of the four size ranges from 0.30 to 1.0 μ m (E_1)
 - 2. The average of the minimum PSE of the four size ranges from 1.0 to 3.0 μ m (E_2)
 - 3. The average of the minimum PSE of the four size ranges from 3.0 to 10.0 μ m (E_3)
 - 4. MERV for the device
- m. Release rate
 - A data table including the information in Figure 11-1d shall be included
- n. Average ASHRAE dust arrestance (for air-cleaning devices with efficiencies less than 20% in the size range of 3.0 to 10.0 µm)
- o. Dust holding capacity (DHC)
- 11.3 Inclusion of test data in the summary report is required. The reported data shall consist of all data recorded during the six test runs and shall be formatted similarly to Figure 11-1e.

12. MINIMUM EFFICIENCY REPORTING VALUE (MERV) FOR AIR CLEANERS

12.1 The minimum efficiency reporting value (MERV) for an air cleaner shall be based on three composite average PSE points developed from tests at the manufacturer's specified airflow rate selected in accordance with Section 8.1. Dust loading shall follow the procedure outlined in Section 10.7,

- and results of the tests shall be reported in accordance with Section 10.8.
- 12.2 The minimum final resistance for an air cleaner shall be the same as or greater than twice the initial resistance.
- 12.3 The minimum efficiency reporting value in the specified size ranges and final resistance for reporting purposes shall be in accordance with Table 12-1. Air cleaners with MERV1 to MERV4 (i.e., devices with efficiencies less than 20% in the size range of 3.0 to 10.0 µm) shall also be tested in accordance with the dust-loading procedure outlined in Section 10.7.2 of this standard before using this system for reporting.
- 12.4 The reporting designator shall be a combination of the air cleaner's MERV and the test airflow rate (e.g., MERV10 at 0.93 indicates that the air cleaner has a MERV10 when tested at 0.93 m³/s [1970 cfm]).
- 12.5 The classification term "MERV" shall only be used in the performance report and product labeling if the entire procedure prescribed by the standard has been included.

13. NORMATIVE REFERENCES

- See informative reference list in Informative Appendix G.
- ASME. 1972. ASME PTC (Performance Test Code) 19.5-72 Application, Part II of Fluid Meters, Sixth Edition 1971, Interim Supplement on Instruments and Apparatus. New York: American Society of Mechanical Engineers.
- 3. See informative reference list in Informative Appendix G.
- ASME. 1989. ANSI/ASME N510, Testing of Nuclear Air Treatment Systems. New York: American Society of Mechanical Engineers.
- ISO. n/d. ISO 12103-1, A2 Fine Test Dust for Filter Evaluation, Part A, Arizona Test Dust. Geneva, Switzerland: International Standards Organization.
- ASTM. 1995. ASTM Standard D3765, Test Method for Carbon Black CTAB Surface Area. Philadelphia, PA: American Society for Testing and Materials.
- ASTM. 1996. ASTM Standard D2414, Test Method for Carbon Black Dibutyl Phthalate Adsorption Number. Philadelphia, PA: American Society for Testing and Materials.
- ASTM. 1995. ASTM Standard D3265, Test Method for Carbon Black Tint Strength. Philadelphia, PA: American Society for Testing and Materials.
- ASTM. 1992. ASTM Standard E437, Industrial Wire Cloth and Screens (Square Opening Series). Philadelphia, PA: American Society for Testing and Materials.
- 10. See informative reference list in Informative Appendix G.
- ASHRAE. 1985. ANSI/ASHRAE Standard 51 (AMCA Standard 210-85), Laboratory Method for Testing Fans for Rating. Atlanta: ASHRAE.
- CRC. 1993. CRC Handbook of Tables for Probability and Statistics, W.H. Beyer, Ed. Cleveland, OH: CRC Press.

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	Page 1 of Cleaner Performance Report Summary pplies to the tested device only)
	Laboratory Data
Report No Tes	t No Date
Test laboratory	
Operator	Supervisor
Particle counter(s): Brand	Model
Device	Manufacturer's Data
Manufacturer	
Product name	Model
Test requested by	
Sample obtained from	
Catalog rating: Airflow ra	teInitial press. drop
Specified test conditions:	Airflow rate
Final pressure drop	Face velocity
De	vice Description
Dimensions: height	widthdepth
Generic name	Media type
Effective media area	Media color
Amount and type of adhesive	e
Other attributes	
Т	Test Conditions
Airflow rate	TemperatureRH
Test aerosol type	
Final pressure drop	Face velocity
Remarks	
Resis	tance Test Results
Initial resistance	Final resistance
Minimum Ef	fficiency Reporting Data
Composite average efficien	cies E ₁ E ₂ E ₃
Air cleaner average Arrest	ance per Std. 52.1
Minimum efficiency reporti	ng value (MERV) for the device:

Figure 11-1a Typical air-cleaner performance report summary.

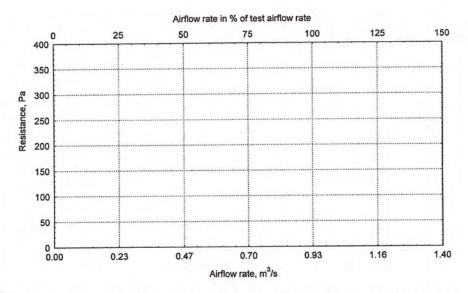


Figure 11-1b Airflow rate vs. resistance of clean device. Illustration is for an air cleaner with a test airflow rate of 0.93 m³/s (1970 cfm).

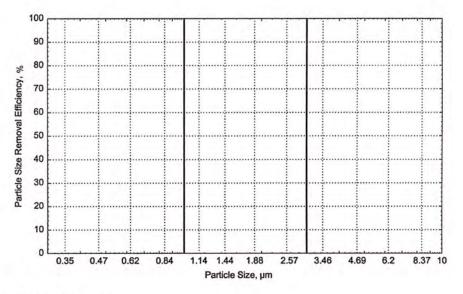


Figure 11-1c Particle size vs. efficiency.

Size Range No.	Geometric Mean of Particle Size Range, µm	Release Rate After Loading Stage 1	Release Rate After Loading Stage 2	Release Rate After Loading Stage 3	Release Rate After Loading Stage 4	Release Rate After Loading Stage 5
1	0.35					
2	0.47					
3	0.62					
4	0.84					
5	1.14					
6	1.44					
7	1.88					
8	2.57					
9	3.46					
10	4.69					
11	6.20					
12	8.37					

Figure 11-1d Release rate data report form.

Size Range No.	Geometric Mean of Particle Size Range, μm	Calculated Particle Size Efficiency, %
1	0.35	
2	0.47	the first transmission and
3	0.62	en lateral to the state of
4	0.84	The state of the state of the state of
5	1.14	Present on a name of the product of
6	1.44	a sunsurances of
7	1.88	
8	2.57	
9	3.46	the control of the co
10	4.69	
11	6.20	and the state of t
12	8.37	I make the a water the same of the case of

Figure 11-1e Test data report form.

Table 12-1 Minimum Efficiency Reporting Value (MERV) Parameters

Standard 52.2	Composite Average	Particle Size Efficiency,	% in Size Range, μm	Description of the second of
Minimum Efficiency Reporting Value (MERV)	Range 1 0.30 to 1.0	Range 2 1.0 to 3.0	Range 3 3.0 to 10.0	Average Arrestance, %
1	N/A	N/A	E ₃ < 20	A _{avg} < 65
2	N/A	N/A	$E_3 < 20$	$65 \le A_{avg}$
3	N/A	N/A	$E_3 < 20$	$70 \le A_{avg}$
4	N/A	N/A	$E_3 < 20$	$75 \le A_{avg}$
5	N/A	N/A	$20 \le E_3$	N/A
6	N/A	N/A	$35 \le E_3$	N/A
7	N/A	N/A	$50 \le E_3$	N/A
8	N/A	$20 \le E_2$	$70 \le E_3$	N/A
9	N/A	$35 \le E_2$	$75 \le E_3$	N/A
10	N/A	$50 \le E_2$	$80 \le E_3$	N/A
11	$20 \le E_1$	$65 \le E_2$	$85 \le E_3$	N/A
12	$35 \le E_1$	$80 \le E_2$	$90 \le E_3$	N/A
13	$50 \le E_1$	85 ≤ <i>E</i> ₂	$90 \le E_3$	N/A
14	$75 \le E_1$	$90 \le E_2$	$95 \le E_3$	N/A
15	$85 \le E_1$	$90 \le E_2$	$95 \le E_3$	N/A
16	$95 \le E_1$	95 ≤ <i>E</i> ₂	$95 \le E_3$	N/A

INFORMATIVE APPENDIX A COMMENTARY

This appendix includes commentary by the project committee. Comments on some of the more important questions that were posed during the writing of this standard relate to the bend in the test duct; the use of a particle's physical size, its aerodynamic size, or its white light-scattering size; dust loading and minimum efficiency reporting; the particle size range covered by the standard; the selection of the test aerosol; and round-robin testing.

A1. BEND IN THE TEST DUCT

The test duct may be constructed with a 180 degree bend downstream of the test device. The bend serves the following purposes:

- a. It brings the downstream sample location relatively close to the upstream location, allowing short sample lines to the particle counter. Because of the physical dimensions and airflow rates involved, particle losses will generally be relatively low per unit length in the test duct and relatively high in sample lines. The bend and additional duct length provide shorter sample line length, reducing overall particle loss.
- It reduces the overall length of the test duct, facilitating its placement within the test room.

A2. DUST LOADING AND MINIMUM EFFICIENCY REPORTING

A2.1 Final resistance from Table 12-1 and dust loading to achieve that final resistance are simply means to identify where the air cleaner's minimum efficiency occurs. They are not intended as recommendations for use or to give any indication of actual service life. Some air cleaners have their lowest efficiency when they are clean (e.g., dry media filters); others have their highest efficiency when they are clean and drop steadily as they are loaded (e.g., electronic air cleaners). Some may drop in efficiency as they begin to be loaded (e.g., electret media) and some start low and then rise in efficiency as they are loaded but may shed dust at the end (e.g., viscous impingement filters).

A2.1.1 Electrostatic Phenomenon Considerations. The test dust and loading procedure specified herein may not be representative of real-world particulate loading and may favor or disfavor air-cleaning devices that rely on electrostatic phenomenon to enhance their performance. The electrostatic phenomenon may be natural or imposed upon the media during manufacturing. As an example of an alternative method for testing electret filters, filtration authorities in the Nordic countries have developed techniques addressing charge-removal efficiencies of fibrous electret filter materials (Reference A1).

A2.2 ASHRAE Technical Committee 2.4 funded a research project (ASHRAE RP-1190) to develop a new loading test method that would more nearly represent the minimum efficiency points in actual real-world use. The results of this research were used to develop a method of conditioning that has been demonstrated in limited cases to more closely predict filter performance in field use. This method of conditioning is now included in this standard as Informative Appendix J with an optional step to help predict the efficiency loss the filter may realize in field applications.

A3. SELECTION OF THE PARTICLE SIZE RANGE

A3.1 This section presents background information and reasons for the selection of the 0.30 to 10 µm particle size range chosen for this standard. This issue was thoroughly debated, not only during the development and monitoring of ASHRAE Research Project RP-671 (Reference A2), on which this standard is based, but also during the deliberations of the committee that formulated this document.

A3.2 The upper size limit of 10 µm was chosen to address the ability of air cleaners to remove potentially irritating and nuisance particles that adversely affect human health and airhandling equipment. Particles of this size may be trapped in the nose and cause irritation and/or allergic reactions. These particles can also soil surfaces and equipment. Such contamination can provide nutrients for biological growth in ductwork or cause duct corrosion, both of which contribute to indoor air quality (IAQ) degradation. Filtration of large particles is needed to protect air-handling systems and equipment from contamination, according to ASHRAE SSPC 62, the standing committee maintaining ANSI/ASHRAE Standard 62.1, Ventilation for Acceptable Indoor Air Quality.

A3.2.1 We recognize that extrapolation from 3 or 5 µm efficiencies to 10 µm is common practice. However, in ASHRAE RP-671 it was demonstrated that "bounce" of 5 to 10 µm particles in low-efficiency air-cleaner media must be taken into account, thus making extrapolation a questionable practice. A Standard 52.2 test report will show particle bounce, if any, in an air cleaner. Refer to Informative Appendix C of this standard, "How to Read a Test Report," for guidance.

A3.2.2 Recirculated air in HVAC systems may contain high concentrations of large particles. Those up to 10 µm are inhalable and affect the health-related aspects of IAQ (Reference A3). Many allergens, fungi, and bioaerosols are in the 3 to 10 µm size range (Reference A4). Large particles can also be carriers of viruses and small bioaerosols.

A3.2.3 Additional factors influenced the selection of the $10~\mu m$ size limit. Particles larger than $10~\mu m$ rarely remain airborne long enough in an indoor space to be carried to the air cleaner. Also, larger particles are difficult to generate and keep in uniform suspension during air-cleaner testing due to their high settling velocities.

A3.3 The primary reason for selecting 0.30 μ m as the lower limit was to permit the test facility to choose from a wide variety of commercially available off-the-shelf particle counters. For example, white-light wide-angle-scattering optical particle counters typically have good monotonic response to polydisperse aerosols, and many have an achievable lower size limit of 0.30 μ m. Expensive or custom-built particle counters are not needed for the tests.

An additional consideration is the limit of the upper-to-lower size range ratio, which is about 30 for most particle counters. Thus, if $10~\mu m$ is the upper size limit, the lower should be $0.30~\mu m$. The ratio becomes critical if the need, cost, and the additional error source of multiple instruments are to be avoided.

A4. SELECTION OF POTASSIUM CHLORIDE AS THE TEST AEROSOL

- A4.1 Particulate potassium chloride (KCl) was chosen as the test aerosol for ASHRAE Research Project RP-671 by consensus among the project monitoring committee and the research contractor. The decision was later unanimously supported by the project committee.
- **A4.2** Nonsynthetic outdoor (ambient) air would have been preferred as the test aerosol but it could not be used for the following reasons:
- a. It lacks a statistically significant quantity of particles $>3~\mu m$. The particle size range of this standard includes sizes up to $10~\mu m$.
- b. It is difficult to obtain reproducible test data from laboratories located in different geographical areas, or even in the same laboratory at different times, without knowing the chemical composition of the ambient aerosol and the size distribution and concentration of the aerosol and rigid control of test hardware. The project committee chose to emphasize performance parameters and relax hardware constraints.
- c. High particle concentrations in sizes <3 μm could overload the particle counter, and inconsistent particle size and shape could produce measurement errors.</p>
- A4.3 Potassium chloride particles have advantages over other synthetic test aerosols because they are easy to generate, have a low cost, are commonly available, and are benign to health. Potassium chloride is also a polydisperse aerosol and has a high critical relative humidity. Commentary follows on other test aerosols that were considered.
- A4.3.1 Monodisperse polystyrene latex (PSL) spheres would require a repeat of the test for each particle size of interest, significantly increasing the time to develop a 0.30 to 10 µm efficiency curve. Although monodisperse PSL aerosols are routinely used for instrument calibration and in small-scale test rigs, it is difficult to generate them in sufficient concentration for the test airflows specified in this standard.
- **A4.3.2** Polydisperse PSL spheres or other polydisperse particles have not been standardized or defined. One type, a latex resin, may be harder to clean up because it is not water soluble.
- A4.3.3 Solid-phase aerosol particles were desired for this standard because they usually present a more severe chal-

lenge to an air cleaner. They frequently bounce off collection surfaces (e.g., fibers), increasing the chance of penetration. Particle sizes >3 µm are most likely to bounce.

A4.3.4 Sodium chloride was also considered, but it was not chosen because the relative humidity of the air must be stringently controlled at less than 55% in order to dry droplets of its solution. KCl droplets dry to solid-phase particles at a relative humidity below ≈70%.

A5. ROUND-ROBIN TESTING

- **A5.1** Many people, including commenters on the first public review draft of this standard, expressed a desire for roundrobin testing before issuing the standard. The committee decided against it for these reasons:
- a. The method is based on ASHRAE RP-671, an advantage that ANSI/ASHRAE Standard 52-68 (and its subsequent revisions) lacked.
- b. Extensive data quality criteria are included in the standard.
- c. Very recent favorable SAE experience with a round-robin on a similar method and European experience in particle size efficiency testing in the 0.20 to 0.50 μm range indicates the validity of the method.
- d. Even if a number of laboratories could be convinced to build the expensive test rig before the standard is accepted and published, and if they were ready to start testing immediately, a round-robin would delay the standard by at least two years.
- **A5.2** In 2001, ASHRAE Technical Committee 2.4 funded an interlaboratory research project to quantify the repeatability and reproducibility of the 52.2-1999 procedures (ASHRAE RP-1088).

A6. APPENDIX A REFERENCES

- A1. NORDTEST. 1996. Development of test methods for electret filters. Technical Report 320, NORDTEST, Espoo, Finland.
- A2. Hanley, J.T., D.D. Smith, and D.S. Ensor. 1993. Define a fractional efficiency test method that is compatible with particulate removal air cleaners used in general ventilation. ASHRAE Research Project RP-671 Final Report, Atlanta, GA.
- A3. Suess, M. 1992. The indoor air quality program of the WHO regional office for Europe. *Proceedings of Indoor Air II*, Copenhagen, Denmark, World Health Organization.
- A4. Foarde, K.K., et al. 1994. Investigate and identify indoor allergens and biological toxins that can be removed by filtration. ASHRAE Research Project RP-760, Final Report, Atlanta, GA.

INFORMATIVE APPENDIX B TEST PROCEDURE SUGGESTIONS AND EXAMPLES

B1. INTRODUCTION

The ability to generate, sample, and measure particles over the 0.30 to $10~\mu m$ diameter size range is critical to the successful performance of a PSE test. The design of an aerosol generation system and an aerosol sampling system believed to meet the required performance criteria of this standard is described in this appendix. These designs are based on those developed in ASHRAE Research Project RP-671. This standard has intentionally made the design of the system elements discretionary so as not to hinder the development and implementation of improved methods.

B2. PARTICLE COUNTER

B2.1 The aerosol concentrations in ASHRAE RP-671 were measured with a single optical particle counter (OPC) using a white-light illumination source and a wide collection angle for

the scattered light. The OPC's sampling rate was 0.00012 m³/s (0.25 cfm).

B2.2 The OPC output was directed to a multichannel analyzer providing the appropriate sizing channels covering the range of 0.30 to 10 μm . The multichannel analyzer was equipped with an interface board providing a contact closure at the end of each sample and a 15 second delay in particle counting after each sample. The contact closure operated electromechanical valves in the upstream and downstream sample lines. The 15 second delay allowed time for the acquisition of a new sample.

B3. AEROSOL GENERATION

B3.1 The test aerosol in ASHRAE RP-671 was solid-phase dry potassium chloride (KCl) in particulate form generated from an aqueous solution. The aerosol was generated by nebulizing an aqueous KCl solution with an external mixing air atomizing nozzle (Figure B-1). The spray nozzle was operated at a relatively low air pressure to keep the particle concentrations in the duct below the coincidence error concentration limit of the particle counter.

B3.2 The nozzle was positioned at the top of a 310 mm (12 in.) diameter, 1300 mm (51 in.) high transparent acrylic spray tower. The tall tower served two purposes: it allowed the salt droplets to dry by providing an approximately 40 second mean residence time, and it allowed larger-sized particles to fall out of the aerosol. An aerosol neutralizer reduced the charge level on the aerosol until the level was equivalent to a Boltzman charge distribution. A Boltzman charge distribution is the average charge found in the ambient air. Electrostatic charging is an

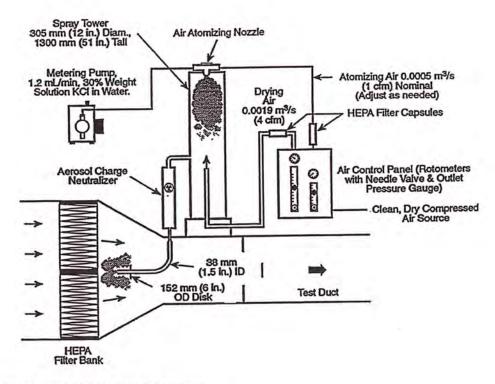


Figure B-1 Schematic of the aerosol generator system.

unavoidable consequence of most aerosol generation methods. The aerosol was injected counter to the airflow, as illustrated in Figure B-1, to improve the mixing of the aerosol with the airstream.

B3.3 The KCl solution was prepared by combining 300 g of KCl with 1 L of distilled water. The solution was fed to the atomizing nozzle at 1.18 mL/min by a metering pump. Varying the operating air pressure of the generator allowed control of the challenge aerosol concentration.

B4. AEROSOL SAMPLING SYSTEM

B4.1 The sampling lines must be carefully designed and constructed to minimize the loss of particles. In ASHRAE RP-671, 14 mm (0.55 in.) ID stainless steel lines and gradual bends (radius of curvature = 57 mm [2.25 in.]) were used. These dimensions were chosen to minimize particle losses within the lines at the sampling rate of 0.00012 m³/s (0.25 cfm).

B4.2 The "Y" fitting connecting the upstream and downstream lines to the particle counter was custom made (Figure B-2). The two branches of the "Y" merge gradually to minimize particle loss in the intersection of the "Y" due to impaction forces.

B4.3 Electrically actuated ball valves were installed in each branch immediately above the "Y." The opening and closing action of the valves was automatically controlled by a relay closure on the particle counter's multichannel analyzer. The valves took approximately two seconds to open or close.

B4.4 Isokinetic sampling nozzles of the appropriate entrance diameter were placed on the ends of the sample probes to maintain isokinetic sampling for all test airflow rates.

B5. EXAMPLES OF AIR-CLEANER EFFICIENCY CALCULATIONS

B5.1 Correlation Calculations

B5.1.1 Figure B-3 shows an example correlation calculation for all particle size ranges. Here a fixed number of samples sets (nine) is used. The correlation ratios R are determined for each particle size range. The resulting correlation ratio error limits,

$$\sigma_c \times \frac{t}{\sqrt{n}}$$

are found for each particle size range and compared to the criteria in Equation 10-11 of Section 10.6.2.1. Also, the correlation ratio maximum background counts $\overline{D}_{b,\,ucl}$, $\overline{U}_{b,\,ucl}$ are calculated and compared to the criteria in Equation 10-12 of Section 10.6.2.3. Lastly, the correlation ratio minimum average upstream counts Avg. $U_{e,c}$ are calculated and compared to the criteria in Equation 10-13 of Section 10.6.2.4.

B5.1.2 Figure B-4 shows an example correlation calculation for a single particle size range. Here the correlation ratio error limit is calculated at the third measurement. The correlation ratio error limit is recalculated for each additional upstream and downstream measurement set. The test can be stopped when the correlation ratio error limit criterion of Section 10.6.2.1 is met.

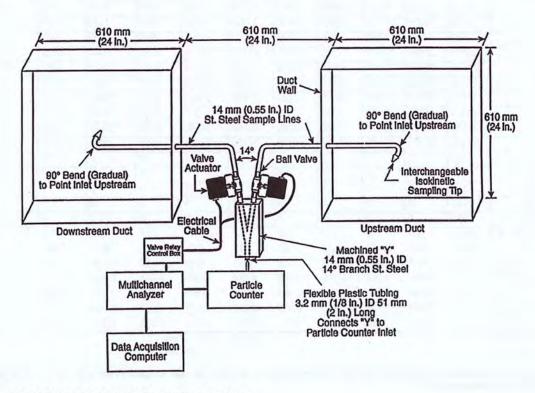


Figure B-2 Schematic of the aerosol sampling system.

33

1 0.35	2 0.45	3 0.55	4 0.69	5 0.89	6 1.22	7	8 2.45	9 3.46	10 4.69	11 6.20	12 8.37
139	0	0	0	0	0	1	0	1	0	0	1
110	0	0	3	0	0	1	1	1	2	1	0
106	1	2	0	1	2	0	0	1	0	1	2
101	3	0	0	0	1	0	0	0	2	0	0
69	0	2	3	1	0	4	4	5	1	9	4
26290	26890	20170	24870	13040	21590	26320	8967	2881	1603	697	440
26390	27240	20410	25320	13260	21830	26310	9273	3040	1688	722	451
26080	26560	19840	24960	13030	21640	26060	9010	2922	1697	732	446
26240	26780	20050	25120	13140	21570	26330	9312	2927	1727	736	428
25530	25590	19330	24360	12600	20810	25520	8724	2777	1619	659	430
Control of the Control	26560	19780	24710	12900	21180	25460	8877	2931	1620	695	456
	25410	19020	24000	12430	20680	25020	8662	2855	1551	657	412
	25650	19250	24220	13070	21130	25620	8909	2857	1647	675	468
24970		19030					8468	2817	1540	612	382
25190	25280	18960	24050	12490	20400	24770	8623	2705	1540	609	406
102	0	1	1	0	0	0	4	1	2	1	0
109	0	0	0	0	02	2	4	2	1	0	0
124	1	0	0	0	0	0	0	0	0	0	0
	1	0	0	0	0	0	1	1	0	0	0
94	0	1	0	0	0	0	1	1	1	0	0
106.5	0.6	0.6	0.7	0.2	0.5	0.8	1.5	1.3	0.9	1.2	0.7
		0.84	1.25	0.42	0.85	1.32	1.78		0.88	2.78	1.34
											1.66
											431.9
0.005	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.005	0.004
125	12	0	1	5	3	14	11	29	16	8	10
	1			0				5		3	1
	1	2	3	0		2	3	4	2	1	2
	5	0	2	2	5	15		11	10	9	13
72	5	3	5	0	1	8		7	6	2	9
25470				12710	and the second						443
26180	26740	20150		13180	21960	26370			1670	675	433
25390	26060	19660	24280	12850	21130	25550			1679	652	461
25880	26580	19950	25240	13020	21580		8942		1632		450
25110	25630	19200	23980	12710	21060	25310	8664	2985	1607	625	455
25310	25830	19530	24110	12820	20920	25070	8655	2961	1570	632	457
25170	25510	19030	24000	12820	20490	25060	8542	2894	1535	618	379
25600	25720	19500	24360	12920	21160	25200	8739	2858	1568	625	439
24570	24710	18690	23480	12200	20290	24650	8439	2724	1602	603	398
24310	24670	18420	23250	12330	20120	24410	8380	2839	1441	610	419
111	0	0	0	0	1	1	0	2	1	0	0
129	1	0	2	0	1	0	0	0	0	0	1
110	3	0	1	- 1	0	3	0	1	1	0	0
105	0	0	0	0	1	0	2	0	0	0	0
114	1	1	0	0	1	5	0	2	0	0	0
105.4	2.9	0.6	1.4	0.8	1.7	5.1	5.4	6.1	3.7	2.3	3.6
18.93	3.70	1.07	1.65	1.62	1.42	5.51	7.37	8.75	5.40	3.43	5.02
118.94	5.54	1.37	2.58	1.96	2.71	9.04	10.67	12.36	7.56	4.76	7.19
0.005	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.004	0.005	0.007	0.017
										10 to 5 d	
0.991	0.988	0.993	0.993	0.995	0.996	0.990	0.981	1.021	0.985	0.931	0.999
0.991 0.017	0.988	0.993	0.993 0.017	0.995	0.996 0.017	0.990	0.981	0.019	0.985	0.931	0.999
	0.35 139 110 106 101 69 26290 26390 26080 25530 25600 24720 25550 24970 25190 102 109 124 111 94 106.5 18.30 119.59 25656 0.005 125 112 102 74 72 25470 26180 25390 2580 25110 25310 25170 25600 24570 24310 111 129 110 105.4 18.93 118.94	0.35 0.45 139 0 110 0 106 1 101 3 69 0 26290 26890 26390 27240 26080 26560 26240 26780 25530 25590 25600 26560 24720 25410 25550 25650 24970 25490 25190 25280 102 0 109 0 124 1 111 1 94 0 106.5 0.6 18.30 0.97 119.59 1.29 25656 26145 0.005 0.000 125 12 112 1 102 1 74 5 25470 25760 26180 26740 25390 26060	0.35 0.45 0.55 139 0 0 110 0 0 106 1 2 101 3 0 69 0 2 26290 26890 20170 26390 27240 20410 26080 26560 19840 26240 26780 20050 25530 25590 19330 25600 26560 19780 24720 25410 19020 25550 25650 19250 24970 25490 19030 25190 25280 18960 102 0 1 109 0 0 124 1 0 111 1 0 144 1 0 115 1.29 1.20 25656 26145 19584 0.005 0.000 0.000 125 <t< td=""><td>0.35 0.45 0.55 0.69 139 0 0 0 110 0 0 3 106 1 2 0 101 3 0 0 69 0 2 3 26290 26890 20170 24870 26390 27240 20410 25320 26080 26560 19840 24960 26240 26780 20050 25120 25530 25590 19330 24360 25550 25650 19780 24710 24720 25410 19020 24000 25550 25650 19250 24220 24970 25490 19030 23780 25190 25280 18960 24050 102 0 1 1 109 0 0 0 124 1 0 0 111 1</td><td>0.35 0.45 0.55 0.69 0.89 139 0 0 0 0 110 0 0 3 0 106 1 2 0 1 101 3 0 0 0 69 0 2 3 1 26290 26890 20170 24870 13040 26390 27240 20410 25320 13260 26080 26560 19840 24960 13030 26240 26780 20050 25120 13140 25530 25590 19330 24360 12600 24720 25410 19020 24000 12430 25550 25650 19250 24220 13070 24970 25490 19030 23780 12580 25190 25280 18960 24050 12490 102 0 1 1 0</td><td>0.35 0.45 0.55 0.69 0.89 1.22 139 0 0 0 0 0 110 0 0 3 0 0 106 1 2 0 1 2 101 3 0 0 0 1 69 0 2 3 1 0 26290 26890 20170 24870 13040 21590 26390 27240 20410 25320 13260 21830 26080 26560 19840 24960 13030 21640 26240 26780 20050 25120 13140 21570 25530 25590 19330 24360 12600 20810 25550 25650 19780 24710 12900 21180 24970 25490 19030 23780 12580 20610 25190 252280 18960 24050 12490<</td><td> 0.35</td><td> 0.35</td><td> 0.35</td><td> 0.35</td><td> 0.35</td></t<>	0.35 0.45 0.55 0.69 139 0 0 0 110 0 0 3 106 1 2 0 101 3 0 0 69 0 2 3 26290 26890 20170 24870 26390 27240 20410 25320 26080 26560 19840 24960 26240 26780 20050 25120 25530 25590 19330 24360 25550 25650 19780 24710 24720 25410 19020 24000 25550 25650 19250 24220 24970 25490 19030 23780 25190 25280 18960 24050 102 0 1 1 109 0 0 0 124 1 0 0 111 1	0.35 0.45 0.55 0.69 0.89 139 0 0 0 0 110 0 0 3 0 106 1 2 0 1 101 3 0 0 0 69 0 2 3 1 26290 26890 20170 24870 13040 26390 27240 20410 25320 13260 26080 26560 19840 24960 13030 26240 26780 20050 25120 13140 25530 25590 19330 24360 12600 24720 25410 19020 24000 12430 25550 25650 19250 24220 13070 24970 25490 19030 23780 12580 25190 25280 18960 24050 12490 102 0 1 1 0	0.35 0.45 0.55 0.69 0.89 1.22 139 0 0 0 0 0 110 0 0 3 0 0 106 1 2 0 1 2 101 3 0 0 0 1 69 0 2 3 1 0 26290 26890 20170 24870 13040 21590 26390 27240 20410 25320 13260 21830 26080 26560 19840 24960 13030 21640 26240 26780 20050 25120 13140 21570 25530 25590 19330 24360 12600 20810 25550 25650 19780 24710 12900 21180 24970 25490 19030 23780 12580 20610 25190 252280 18960 24050 12490<	0.35	0.35	0.35	0.35	0.35

^{*} For limits, see Section 10.6.2.4.

Figure B-3 Example correlation calculations for n = 9 sample sets in all particle size ranges. From run 1 of 5, 100% penetration test, ASHRAE RP-671 (Reference A1).

[†] For limits, see Section 10.6.2.3.

^{**} For limits, see Section 10.6.2.3

^{††} For limits, see Section 10.6.2.1.

i	$U_{i,o,c}$	$D_{i,o,c}$	$U_{i,e,c}$	R_i	\overline{R}	δ_c	\overline{R}_{lcl}	\overline{R}_{ucl}	$\delta_c \times \frac{t}{\sqrt{t}}$
1	26290	25470	26340	0.967					
2	26390	26180	26235	0.998	0.982	0.022			
3	26080	25390	26160	0.971	0.978	0.017	0.936	1.021	0.042
4	26240	25880	25885	1.000	0.984	0.017	0.956	1.012	0.028
5	25530	25110	25565	0.982	0.983	0.015	0.965	1.002	0.019
6	25600	25310	25160	1.006	0.987	0.016	0.970	1.004	0.017
7	24720	25170	25135	1.001	0.989	0.016	0.975	1.004	0.015
8	25550	25600	25260	1.013	0.992	0.017	0.978	1.006	0.014
9	24970	24570	25080	0.980	0.991	0.016	0.978	1.004	0.013
10	25190	24310							

Figure B-4 Example correlation calculation for one particle size range with error evaluation at each step. From run 1 of 5, size range 1, 100% penetration tests, ASHRAE RP-671 (Reference A1).

B5.2 Penetration Calculations

B5.2.1 Figure B-5 shows an example penetration calculation for all particle size ranges. Here a fixed number of samples sets (nine) is used. The penetration ratios P are determined for each particle size range. The resulting penetration ratio error limits,

$$\sigma_c \times \frac{t}{\sqrt{n}}$$

are found for each particle size range and compared to the criteria in Equation 10.23 of Section 10.6.4.1. Also, the penetration ratio maximum background counts $\overline{D}_{b,\,ucl},\,\overline{U}_{b,\,ucl}$ are calculated and compared to the criteria in Equation 10-24 of Section 10.6.4.2. Lastly, the penetration ratio minimum average upstream counts Avg. $U_{e,t}$ are calculated and compared to the criteria in Equation 10-25 of Section 10.6.4.3.

B5.2.2 Figure B-6 shows an example penetration calculation for a single particle size range. Here the penetration ratio error limit is calculated at the third measurement. The penetration ratio error limit is recalculated for each additional upstream and downstream measurement set. The test can be stopped when the penetration ratio error limit criterion of Section 10.6.4.1 is met.

B6. TEST SEQUENCE

The following tabulation of the test sequence steps may help to clarify the procedure:

Step	Air Cleaner	KCI Gene	rator	Dust Feed	
1. Correlation ratio	None		On	Off	
2. Resistance vs. airflow	In place	Off		Off	
3. Initial PSE test	In place		On	Off	
4. First dust loading	In place	Off			On
5. PSE test	In place		On	Off	
6. Second dust loading	In place	Off			Or
7. PSE test	In place		On	Off	
8. Third dust loading	In place	Off			Or
9. PSE test	In place		On	Off	
10. Fourth dust loading	In place	Off			Or
11. PSE test	In place		On	Off	
12. Fifth dust loading	In place	Off			On
13. PSE test	In place		On	Off	

a. Background counts In place Off Off
b. Efficiency measurement In place Off Off
c. Background In place Off Off

Prior to each dust loading, the duct airflow is turned off, the filter is installed, and the particle counters' inlet probes are capped. The duct airflow is then resumed.

After each dust loading, the duct airflow is turned off, the particle counters' inlet probes are uncapped, and the final filter is removed. The duct airflow is then resumed.

OPC Channel # Geo. Mean Dia. (μm)	1 0.35	0.45	3 0.55	4 0.69	5 0.89	6	7 1.73	8 2.45	9 3.46	10 4.69	6.20	12 8.37
Upstream—Bkg	147	2	1	2	0	0	1	-1	0	0	2	- 1
Upstream—Bkg	308	77	7	2	0	2	0	0	0	0	0	0
Upstream—Bkg	174	0	0	0	0	0	0	0	0	0	0	0
Upstream—Bkg	184	1	0	0	0	0	0	0	0	0	0	(
Upstream—Bkg	169	0	0	0	0	0	0	0	0	0	0	0
Upstream	21850	21770	16280	19670	10280	16830	21570	7618	2505	1376	547	321
Upstream	20820	20880	15270	18580	9843	16090	20680	7189	2479	1329	470	305
Upstream	21350	21040	15600	19160	9977	16500	20980	7314	2499	1332	511	332
Upstream	22630	22460	16420	20320	10660	17400	22360	7876	2620	1395	531	314
Upstream	21560	21210	15730	19260	10030	16800	21010	7348	2393	1270	536	291
Upstream	22240	21940	16060	19780	10390	17340	21530	7565	2557	1276	552	303
Upstream	22680	22170	16430	20180	10410	17620	22490	7546	2503	1362	546	324
Upstream	22590	21990	16550	19980	10410	17620	22360	7578	2576	1325	548	297
	23300	22980	16580	20660	10650	17730	22460	7706	2574	1329	498	300
Upstream		23480	17180	21150	11180	18260	23480	8175	2675	1453	516	325
Upstream Pkg	23850		_			18200	23480		2073	1433	0	323
Upstream—Bkg	147	5	0	2	0	0	1	5	2	0	0	(
Upstream—Bkg	159	0	2	0	0	1	0	2	0	0	0	(
Upstream—Bkg	142			_			0		_	- 1	0	1
Upstream—Bkg	135	0	0	1	0	0	1	2	0	0	-	- 1
Upstream—Bkg	113	0	0	0	0	0	1	0	3	2	2	(
Avg. U_b	167.8	8.6	1	0.7	0	0.8	0.9	1.2	0.7	0.4	0.4	0.2
Std. Dev. U_b	53.38	24.08	2.21	0.95	0.00	1.32	1.20	1.62	1.16	0.70	0.84	0.42
$U_{b, ucl}$	205.98	25.83	2.58	1.38	0.00	1.74	1.76	2.36	1.53	0.90	1.00	0.50
Avg. $U_{t_{\star}}^{*}$	22287	21992	16210	19874	10387	17219	21892	7591.5	2538.1	1344.7	525.5	311.2
$U_{b,ucl}/\text{Avg}. U_{l}^{\dagger}$	0.009	0.001	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.002
Downstream—Bkg	157	0	1	0	0	0	2	1	1	0	1	0
Downstream—Bkg	207	1	2	1	0	1	1	2	0	1	0	1
Downstream—Bkg	167	0	1	1	0	2	3	2	2	0	0	0
Downstream—Bkg	164	0	1	1	1	1	7	12	4	1	1	1
Downstream—Bkg	170	2	2	1	2	2	1	1	1	0	1	2
Downstream	17450	16070	11070	11840	4955	6220	3506	271	34	13	5	2
Downstream	17060	16080	10800	11540	4880	5969	3449	305	37	23	2	3
Downstream	17480	16480	10960	12040	5122	6288	3644	319	41	15	2	7
Downstream	18640	17170	11590	12550	5264	6379	3813	303	42	11	6	3
Downstream	17180	15760	10770	11540	4859	6053	3497	272	24	10	7	2
Downstream	18350	16740	11440	12200	5134	6251	3607	317	39	14	3	5
Downstream	18220	16780	11300	12000	5091	6239	3608	298	40	11	6	3
Downstream	18500	17190	11590	12300	5180	6442	3720	302	42	15	6	3
Downstream	18970	17780	12170	12620	5470	6745	3851	303	53	17	9	2
Downstream	19450	18030	12380	13330	5667	6940	3995	263	37	13	3	1
Downstream—Bkg	189	14	1	0	0	0	0	0	0	0	0	0
Downstream—Bkg	138	0	1	0	0	0	0	0	0	0	0	0
Downstream—Bkg	161	0	0	0	0	1	0	2	1	2	1	0
Downstream—Bkg	136	0	0	0	0	0	1	0	0	0	0	0
Downstream—Bkg	139	1	0	0	0	0	0	3	1	1	1	0
Avg. D_b	162.8	1.8	0.9	0.4	0.3	0.7	1.5	2.3	1	0.5	0.5	0.4
Std. Dev. D_h	22.72	4.34	0.74	0.52	0.67	0.82	2.17	3.56	1.25	0.71	0.53	0.70
	179.05	4.91	1.43	0.32	0.78	1.29	3.05	4.85	1.89	1.01	0.88	0.90
$D_{b, ucl}/Avg. U_l^{**}$	0.008	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.001	0.002	0.003
						0.000	0.990	0.001	1.021	0.985	0.002	0.003
R Ctd Down R	0.991	0.988	0.993	0.993	0.995							
Std. Dev. R	0.808	0.761	0.699	0.609	0.493	0.366	0.166	0.039	0.015	0.010	0.009	0.009
Std. Dev. R'/n ^{0.5}	0.815	0.770	0.704	0.613	0.496	0.367	0.168	0.040	0.015	0.010	0.009	0.009
Std. Dev. P_o	0.017	0.015	0.015	0.012	0.009	0.009	0.004	0.002	0.003	0.003	0.005	0.005
Std. Dev. R	0.017	0.019	0.021	0.017	0.017	0.017	0.011	0.017	0.019	0.022	0.031	0.062
Std. Dev. P	0.022	0.021	0.021	0.017	0.012	0.011	0.005	0.002	0.003	0.003	0.005	0.005
Std. Dev. $P \times t/n^{0.5 \dagger \dagger}$	0.017	0.016	0.016	0.013	0.010	0.008	0.003	0.002	0.002	0.002	0.004	0.004

^{*} For limits, see Section 10.6.4.4.

Figure B-5 Example penetration calculations for n = 9 sample sets in all particle size ranges. From run 1 of 3, pleated paper filter tests, ASHRAE RP-671 (Reference A1).

[†] For limits, see Section 10.6.4.2.

^{**} For limits, see Section 10.6.4.2.

^{††} For limits, see Section 10.6.4.1.

i	$U_{i,o,t}$	$D_{i,o,t}$	$U_{i,e,t}$	$P_{i,o}$	\overline{P}_o	\overline{P}	δ_t	d	$ar{P}_{lcl}$	\overline{P}_{ucl}	$\delta_c \times \frac{t}{\sqrt{n}}$
1	21850	17450	21335	0.818	II rom	T-T-	and a series of	in mining	n non A	ti i in grid	ni kana kana
2	20820	17060	21085	0.809	0.814	0.820	0.006	0.015	SERT MARKET	State of the state	
3	21350	17480	21990	0.795	0.807	0.814	0.012	0.018	0.762	0.836	0.045
4	22630	18640	22095	0.844	0.816	0.823	0.020	0.025	0.777	0.849	0.039
5	21560	17180	21900	0.784	0.810	0.816	0.023	0.027	0.777	0.838	0.033
6	22240	18350	22460	0.817	0.811	0.817	0.021	0.025	0.785	0.833	0.026
7	22680	18220	22635	0.805	0.810	0.817	0.019	0.023	0.789	0.828	0.022
8	22590	18500	22945	0.806	0.810	0.816	0.018	0.022	0.791	0.824	0.019
9	23300	18970	23575	0.805	0.809	0.816	0.017	0.022	0.793	0.822	0.017
10	23850	19450	yen hos et	-/ blim	n nila n					Ballo Is	o made of

Figure B-6 Example penetration calculation for one particle size range with error evaluation at each step, where δ_o = 0.017 and R = 0.992. From run 1 of 3, size range 1, pleated paper filter tests, ASHRAE RP-671 (Reference A1).

INFORMATIVE APPENDIX C HOW TO READ A TEST REPORT

This appendix is meant to provide background information about the test report and explanations in layman's terms for users (building owners, installers, and design engineers).

C1. BACKGROUND

- C1.1 ASHRAE does not actually test air cleaners or determine their performance but only promulgates the test procedure used by manufacturers and independent testing laboratories.
- C1.2 Air-cleaner testing in a laboratory is intended to help the user compare the performance of different types of air cleaners. Testing attempts to simulate the performance of air cleaners in real-life operation but cannot duplicate field conditions. Field conditions vary from location to location. The reporting values obtained in accordance with this standard cannot be used by themselves to predict the air cleanliness of a specific ventilated space or the service life of installed air cleaners.
- C1.3 Testing accelerates the life experience of an air cleaner, and accelerated use is different from normal use. The ASHRAE test involves concentrations and compositions that are almost certain to be different from those the air cleaner will encounter when installed in a system. Also, the airflow rate, final resistance, and temperature and humidity level of the air may be different in the testing laboratory from those on the job.
- C1.4 Laboratory accuracy is expected of the instrumentation used in testing to the standard. However, this does not mean that the tested filter will perform with laboratory accuracy on an installed job.

C2. READING A TEST REPORT

- C2.1 The summary section of a sample performance report on a typical extended-surface media filter is shown in Figures C-1, C-2, and C-3. The circled numbers refer to the explanations that follow.
- The test method should be in accordance with the latest edition of the ASHRAE standard.
- These sections are helpful to trace the test laboratory, test owner, and test specimen.
- This information is important for identification. Upon request, independent test laboratories will verify data with users and identify any tampering with the results.
- This information is useful because different types of detecting devices may give differing readings. Good calibration is most necessary.
- Manufacturers' catalog data are not required by the standard, but if such data are included in the test report, it will

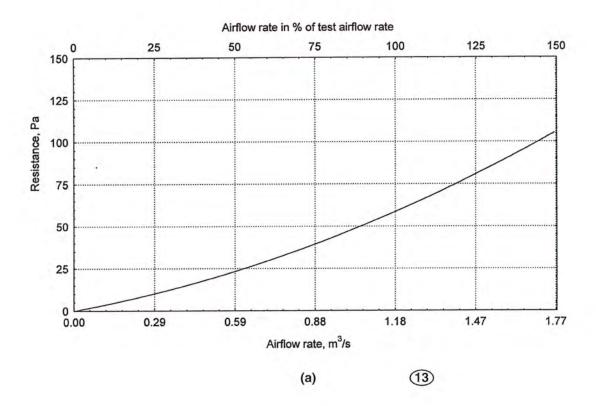
- help the user compare published data and actual performance.
- 6. The test airflow rate is specified by the manufacturer and generally depends on the filter size (height, width, and depth), media area, and construction. The airflow rate must be between 0.22 and 1.4 m³/s (472 and 2990 cfm) and be selected from Section 8.1.
- Device manufacturers must specify the final resistance for testing using Table 12-1 values as minimums.
- The physical description must match the filter being considered. This part is very important because there are many filters with the same name and a different appearance (fewer pockets, longer pockets, etc.).
- The test airflow rate and net effective media area may be used to calculate media velocity:

Media velocity, m/s (fpm) =
$$\frac{\text{Airflow rate, m}^3/\text{s(cfm)}}{\text{Effective media area, m}^2(\text{ft}^2)}$$

- 10. Note that the performance of a manufactured filter will usually be very different from that of a flat sheet of the media used to construct the filter.
- 11. The initial resistance is the resistance to airflow of the filter at the test airflow rate. Depending on the design and construction of the filter, initial resistance may or may not indicate life expectancy.
- 12. These minimum averages help to define the minimum performance of the device in removing particles of various sizes. They are not full averages.
- 13. The MERV is based on the minimum PSEs and Table 12-1. The reporting value helps the user select an air cleaner but does not reflect the total behavior of the device.
- 14. This curve shows the resistance of the clean filter over the prescribed range of face velocities.
- These curves show the PSE after loading with incremental amounts of dust.
- 16. This curve shows the minimum values of PSE during the test. Refer to Informative Appendix D for examples of the use of this curve.
- 17. The dust-holding capacity presents the total weight of synthetic loading dust captured by the air-cleaning device over all of the incremental dust loading steps. This value should not be used to calculate the expected life of the device in use.
- 18. The average dust arrestance presents the ability of the filter to remove loading dust from test air. This is measured and reported only for air-cleaning devices with efficiencies less than 20% in the size range of 3.0 to 10.0 μm.
- 19. The release rate gives an indication of filter shedding.
- 20. This curve shows the resistance vs. synthetic loading dust fed (for air-cleaning devices with efficiencies less than 20% in the size range of 3.0 to $10.0 \mu m$).

Page 1 of 3
ASHRAE Std. 52.2 Air Cleaner Performance Report Summary
O (This report applies to the tested device only)
Laboratory Data 3
Report No. 99-392 Test No. 99-1798 Date DEC. 12, 1999
Test laboratory INDEPENDENT TEST LAS, INC.
Operator 7. SM:7H Supervisor & SUPER
Particle counter(s): Brand COUNTALL Model 226/80 Device Manufacturer's Data 3
Manufacturer_ FILTERMAKER, NC.
Product name FLO-RITE Model 12
Test requested by FILTER SALES CO.
Sample obtained from OPEN MARKET 3
Catalog rating: Airflow rate 1.18 m 3/s Initial press. drop 53 Pa
Specified test conditions: Airflow rate 1.18 m 3/5
Final pressure drop 250 Pa ② Face velocity 3.2 m/s
Device Description ②
Dimensions: height 590 mm width 590 mm depth 560 mm
Generic name BAG FILTER Media type SYN. NON NOVEN POLYESTER.
Effective media area 3.5 m² 9 Media color YELLOW
Amount and type of adhesive NONE
Other attributes 5 Pocke75
Test Conditions
Airflow rate 1.18 m 3/3 Temperature 22°C RH 50%
Test aerosol type KCI
Final pressure drop 250 Pa Face velocity 3.2 m/s
Remarks_ NONE
Resistance Test Results
Initial resistance 57 Pa @ Final resistance 250 Pa
Minimum Efficiency Reporting Data Composite average efficiencies E ₁ 13% E ₂ 60% E ₃ 87% Air cleaner average Arrestance N/A
Composite average efficiencies E ₁ 13% E ₂ 60% E ₃ 8770
Minimum efficiency reporting value (MERV) for the device:
Dust Holding Capacity (g) 693 (6) MERV 10 @ 1.18 (2)

Figure C-1 Sample summary air-cleaner performance report, Page 1.



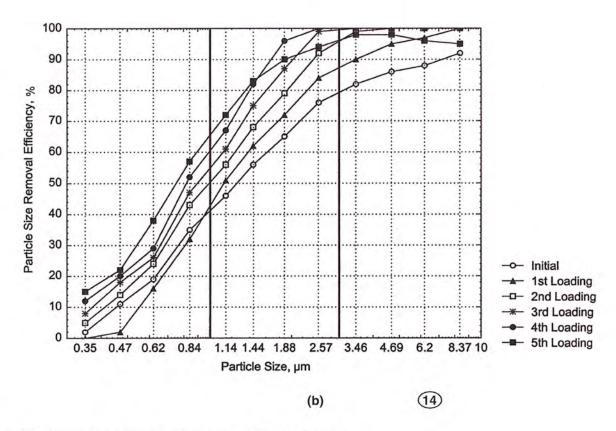


Figure C-2 Sample air-cleaner performance report summary, Page 2.

- (a) Resistance of clean device vs. airflow.
- (b) PSE after incremental dust loading.

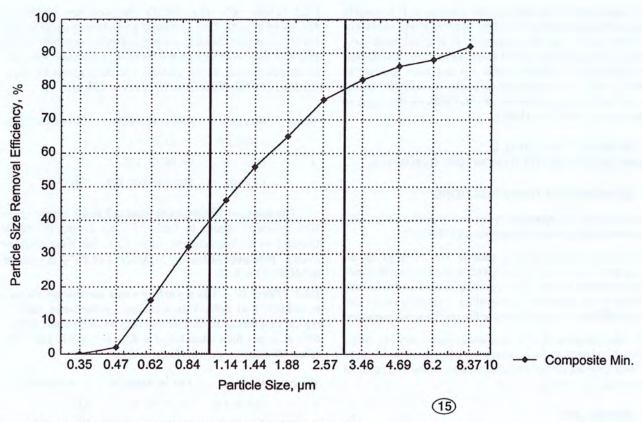


Figure C-3 Sample air-cleaner performance report summary, Page 3.

—Composite minimum efficiency curve.

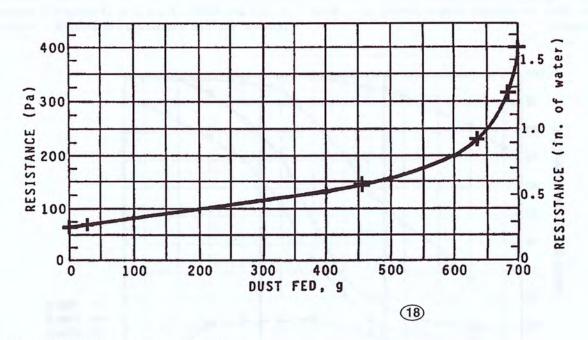


Figure C-4 Sample air-cleaner report summary, Page 3.

—Resistance vs. Synthetic Loading Dust Fed graph ONLY for air-cleaning devices with efficiencies less than 20% in the size range of 3.0 to 10.0 μm).

INFORMATIVE APPENDIX D MINIMUM EFFICIENCY REPORTING GUIDANCE

D1. GENERAL RECOMMENDATIONS

The purpose of this appendix is to provide guidance in using the system and show some examples of MERVs.

D1.1 Removal efficiency vs. particle size tests of an air cleaner as it is loaded with dust yields a set of curves that may be inconvenient to use. This reporting system simplifies the selection of air cleaners by providing a single particle size removal efficiency reporting value for specification purposes.

D1.2 Any reporting system is a compromise and can never reflect all the performance parameters of an air cleaner. Manufacturer data should be consulted whenever specific removal performance is desired.

D2. EXAMPLES

Examples of typical minimum efficiency curves are shown in Figure D-1. Each curve is the minimum performance of the air cleaner from the initial test of the clean device to the test at its final loading stage. It will be helpful to have Table 12-1 readily available for reference when reviewing these curves and the method.

D2.1 "Filter A"—The MERV for this air cleaner is MERV14 at 0.93. This minimum performance curve is typical of a media air cleaner currently marketed as a 90% to 95% dust spot filter when tested at 0.93 m³/s (1970 cfm). The minimum efficiencies for the particle size ranges must be calculated to report the filter. The PSEs are as follows:

Range	Size, μm	PSE in Range,%	Average PSE,%
1	0.30 to 1.0	74, 82, 87, 92	84
2	1.0 to 3.0	96, 98, 99, 100	98
3	3.0 to 10	100, 100, 100, 100	100

The average efficiencies in Ranges 2 and 3 are above the 90% minimum shown in Table 12-1 for a filter in MERV Group 1 to 4. According to Table 12-1, this filter, with an average minimum efficiency in Range 1 of 84%, is reported as MERV14 at 0.93.

D2.2 "Filter B"—The reporting value for this air cleaner is MERV11 at 0.93. This minimum performance curve is typical of a media air cleaner currently marketed as a 60% to 65% dust spot filter when tested at 0.93 m³/s (1970 cfm). The range efficiencies are calculated as follows:

Range	Size, µm	PSE in Range,%	Average PSE,%
1	0.30 to 1.0	18, 28, 38, 47	33
2	1.0 to 3.0	58, 72, 84, 96	78
3	3.0 to 10	98, 99, 99, 99	99

The average efficiency in Range 3 is above the 85% and 90% minimums shown in Table 12–1 for the MERV Group 9 to 12 and MERV Group 13 to 16 categories, respectively. However, the filter is categorized in the MERV Group 9 to 12

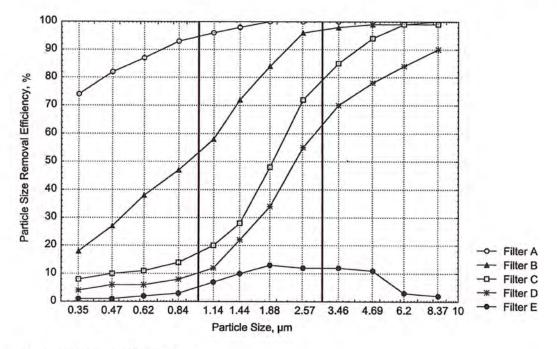


Figure D-1 Typical minimum efficiency curves.

area since the average efficiency in Range 2 is below the 90% minimum requirement for the MERV Group 13 to 16 category. The average efficiency in Range 1 is not used for reporting. Based on the average efficiency of 78% in Range 2, the filter is reported as MERV11 at 0.93.

D2.3 "Filter C"—The reporting value for this air cleaner is MERV9 at 0.93. This minimum performance curve is typical of a media air cleaner currently marketed as a 40% to 45% dust spot filter when tested at 0.93 m³/s (1970 cfm). As in the examples above, the range efficiencies are calculated as follows:

Range	Size	PSE in Range,%	Average PSE,%
1	0.30 to 1.0	8, 10, 11, 14	11
2	1.0 to 3.0	20, 28, 48, 72	42
3	3.0 to 10	85, 94, 98, 99	94

The average efficiency in Range 3 is above the 85% and 90% minimums shown in Table 12-1 for the MERV Group 9 to 12 and MERV Group 13 to 16 categories, respectively. The filter is categorized in the MERV Group 9 to 12 area because the average efficiency in Range 2 is below the 90% minimum requirement for the MERV Group 13 to 16 category. The average efficiency in Range 1 is not used for reporting. Based on the average efficiency of 42% in Range 2, this filter is reported as MERV9 at 0.93.

D2.4 "Filter D"—The reporting value for this air cleaner is MERV8 at 0.93. This minimum performance curve is typical of a media air cleaner currently marketed as a 25% to 30% dust spot filter when tested at 0.93 m³/s (1970 cfm). The range efficiencies are calculated as follows:

Range	Size	PSE in Range,%	Average PSE,%
1	0.30 to 1.0	5, 6, 6, 8	6
2	1.0 to 3.0	12, 22, 33, 55	31
3	3.0 to 10	70, 78, 84, 90	81

The average efficiency in Range 3 is in the 80% to 85% range shown in Table 12-1 for the MERV Group 10 category. However, the E2 value is above the 20% required for MERV 8 and below the 35% required for MERV 9. Thus, the MERV of this filter is reported as MERV 8 at 0.93.

D2.5 "Filter E"—The dust-loading test in this standard cannot be used to report this air cleaner. This minimum performance curve is typical of a media air cleaner currently marketed as a "furnace" filter. The average efficiencies are below the 20% minimum requirement shown in Table 12-1 for MERV Group 5 to 8:

Range	Size, μm	PSE in Range,%	Average PSE,%
1	0.30 to 1.0	1, 1, 2, 3	2
2	1.0 to 3.0	8, 10, 13, 12	11
3	3.0 to 10	12, 11, 4, 2	7

The filter is classified as MERV Group 1 to 4 and must be tested in accordance with the arrestance method outlined in Section 10.7 of this standard. The air cleaner can then be reported in accordance with Table 12-1 using the average arrestance value.

D3. CONCLUSIONS

In most cases, comparisons of air cleaners of similar type and material will yield good relationships between laboratory and field conditions. However, the user must be aware that the tests are made under laboratory conditions using synthetic dust for loading. The synthetic dust used to load the test air cleaner is not representative of all atmospheric particulates, and, thus, tests on some types of air cleaners may be affected favorably or otherwise.

INFORMATIVE APPENDIX E CROSS-REFERENCE AND APPLICATION GUIDELINES

E1. INTRODUCTION

- E1.1 The purpose of this appendix is to provide an approximate cross reference of Standard 52.1-1992 reporting methods (arrestance and atmospheric dust-spot efficiency) to the air-cleaner minimum efficiency reporting system outlined in Section 12. A corollary purpose is to provide application guidance to the user and HVAC system designer. To do this most effectively, HEPA/ULPA filters have been added to the reporting system. HEPA/ULPA filters have been assigned MERVs based on their performance in accordance with Institute of Environmental Sciences and Technology (IEST) standards. Table E-1 combines all of the parameters into a single reference covering most general ventilation air-cleaner types and applications.
- E1.2 A single performance measurement system cannot be applied precisely to all types and styles of air cleaners. Each air cleaner has unique characteristics that change during its useful life. Also, the particle size efficiency test method in this standard does not eliminate the need for dioctyl phthalate (DOP) penetration and arrestance testing. This new reporting system may, however, eventually replace the arrestance and atmospheric dust-spot and DOP efficiency reporting values as performance references.
- **E1.3** Typical contaminants listed in Table E-1, "Application Guidelines," appear within the general reporting group that removes the smallest known size of that particular contaminant. The order in which they are written has no significance, nor is the list complete.
- E1.4 Typical applications and typical air-cleaner types listed are intended to show where and what type air cleaner is traditionally used. The order in which they are written has no significance, nor is the list complete. Traditional use may not represent the optimum choice, so using the table as a selection guide is not appropriate when a specific performance requirement is needed. Consultation with an air-cleaner specialist is then advisable, and manufacturer's performance curves should be reviewed.

- E1.5 Some knowledge of how air cleaners work and common sense will also help the user achieve satisfactory results. Air-cleaner performance varies from the time it is first installed until it reaches the end of its service life. Generally, the longer a media-type filter is in service, the better it performs. The accumulation of contaminants begins to close the porous openings and, therefore, the filter is able to intercept particles of smaller size. However, there are exceptions that vary with different styles of media-type filters.
- E1.6 Some air cleaners, particularly those in the lower part of the minimum efficiency reporting values, may begin to shed some of the collected contaminants after varying lengths of service life. Testing with standardized synthetic loading dust attempts to predict this occurrence, but this will rarely, if ever, duplicate performance on atmospheric dust.

E2. AIR-CLEANER EFFECTIVENESS

Three factors determine the effectiveness of an air cleaner to treat the air in an occupied space: air-cleaner efficiency, the amount of air being filtered, and the path that the clean air follows after it leaves the filter.

- E2.1 As an example of the interaction of air-cleaner efficiency and airflow rate, portable self-contained (fan and filter) air-cleaner effectiveness is often measured by the clean air delivery rate (CADR), which is the combined effect of how much air actually is moved through the filter and the efficiency of the filter. A high-efficiency air filter in an air cleaner with a low airflow rate can have a lower CADR than one with a lower MERV air filter but higher airflow volume.
- E2.2 An airflow path considered best would be one that would enter the space where the cleanest air is required, flow without turbulence through 100% of the space toward the point where cleanliness is least important (perhaps near the floor), and then return to the air cleaner. These ideal conditions can rarely be met, so most installations must be a compromise between what is desired and what is practical.
- E2.3 Air cleaners are tested under ideal laboratory conditions where care is taken to prevent leakage of air around them. Totally leak-free hardware is unusual in HVAC equipment, so air cleaners rarely perform to the same degree of effectiveness under field conditions. Only extreme care in finding and sealing all the leak paths in the hardware and in ductwork between the filter and the fan will ensure full performance of the air cleaner.
- **E2.4** Table E-1, "Application Guidelines" covers particulate contamination control only, as does this standard. Gaseous contaminant control is also important in many systems but is not addressed in this guideline.

Table E-1 Application Guidelines

Std. 52.2 Minimum	Application Guidelines				
Efficiency Reporting Value (MERV)	Typical Controlled Contaminant	Typical Applications and Limitations	Typical Air Filter/Cleaner Type		
16	0.30 to 1.0 μm Particle Size All bacteria	Hospital inpatient care General surgery	Bag Filters Nonsupported (flexible) microfine fiberglass or synthetic		
15	Most tobacco smoke Droplet nuclei (sneeze)	Smoking lounges Superior commercial	media. 300 to 900 mm (12 to 36 in.) deep, 6 to 12 pockets. Box Filters		
14	Cooking oil Most smoke	buildings	Rigid style cartridge filters 150 to 300 mm (6 to 12 in.) deep may use lofted (air laid) or paper (wet laid)		
13	Insecticide dust Copier toner Most face powder Most paint pigments		media.		
12	1.0 to 3.0 µm Particle Size Legionella	Superior residential Better commercial	Bag Filters Nonsupported (flexible) microfine fiberglass or synthetic		
11	Humidifier dust Lead dust	buildings Hospital laboratories	media. 300 to 900 mm (12 to 36 in.) deep, 6 to 12 pockets. Box Filters		
10	Milled flour Coal dust		Rigid style cartridge filters 150 to 300 mm (6 to 12 in.) deep may use lofted (air laid) or paper (wet laid)		
9	Auto emissions Nebulizer drops Welding fumes		media.		
8	3.0 to 10.0 µm Particle Size Mold	Commercial buildings Better residential	Pleated Filters Disposable, extended surface, 25 to 125 mm		
7	Spores Hair spray	Industrial workplaces Paint booth inlet air	(1 to 5 in.) thick with cotton-polyester blend media, cardboard frame.		
6	Fabric protector Dusting aids		Cartridge Filters Graded density viscous coated cube or pocket filters,		
5	Cement dust Pudding mix Snuff Powdered milk		synthetic media. Throwaway Disposable synthetic media panel filters.		
4	>10.0 µm Particle Size Pollen	Minimum filtration Residential	Throwaway Disposable fiberglass or synthetic panel filters		
3	Spanish moss Dust mites	Window air conditioners	Aluminum mesh, latex coated animal hair, or foam rubber		
2	Sanding dust Spray paint dust		panel filters Electrostatic		
1	Textile fibers Carpet fibers		Self charging (passive) woven polycarbonate panel filter		

Note: A MERV for other than HEPA/ULPA filters also includes a test airflow rate, but it is not shown here because it has no significance for the purposes of this table.

INFORMATIVE APPENDIX F ACRONYMS AND CONVERSION FORMULAE

F1. ACRONYMS

CADR Clean air delivery rate IAQ Indoor air quality

IEST Institute of Environmental Sciences

and Technology

OPC Optical particle counter

For the meanings of other acronyms, refer to Section 3.2.

F2. CONVERSION FORMULAE

The following units and conversions may be useful in using this standard.

1 m 3.2808 ft 1 m^2 10.764 ft² 1 m^3 35.315 ft3 1 m/s 196.85 fpm $1 \text{ m}^3/\text{s}$ 2118.9 cfm $1 \text{ m}^3/\text{s}$ 1000 L/s 1 m³/min 35.315 cfm $1 \text{ m}^3/\text{h}$ 0.5886 cfm $1 \text{ cm}^3/\text{s}$ 0.00212 cfm 0.00402 in. of water 1 Pa

A converted value is no more precise than the original value. The final value should be rounded off to the same number of significant figures as the original value.

INFORMATIVE APPENDIX G INFORMATIVE REFERENCES

The following references are cited for information only. Normative references are located in Section 13 of the standard.

- ASHRAE. 1991. ASHRAE Terminology of Heating, Ventilation, Air Conditioning, & Refrigeration, Second Edition. Atlanta: ASHRAE.
- 2. See normative references in Section 13.

- Riehl, J., V.R. Dileep, N.K. Anand, and A.R. McFarland. 1996. DEPOSITION 4.0: An Illustrated User's Guide. Report 8836/07/96, Aerosol Technology Laboratory, Department of Mechanical Engineering, Texas A&M University, College Station, TX.
- 4. See normative references in Section 13.
- 5. See normative references in Section 13.
- 6. See normative references in Section 13.
- 7. See normative references in Section 13.
- 8. See normative references in Section 13.
- 9. See normative references in Section 13.
- ASME. 1989. ASME Standard MFC-3M, Measurement of Fluid Flow in Pipes Using Orifices, Nozzles and Venturi. New York: American Society of Mechanical Engineers.
- 11. See normative references in Section 13.
- 12. See normative references in Section 13.

INFORMATIVE APPENDIX H ADDENDA DESCRIPTION INFORMATION

ANSI/ASHRAE Standard 52.2-2017 incorporates ANSI/ASHRAE Standard 52.2-20012 and Addenda a, b, c, d, e, f, g, and i to ANSI/ASHRAE Standard 52.2-2012. Table H-1 lists the addendum and describes the way in which the standard is affected by the change. It also lists the ASHRAE and ANSI approval dates for the addendum.

Table H-1 Addenda to ANSI/ASHRAE Standard 52.2-2012

Addendum	Sections Affected	Description of Changes*	ASHRAE Standards Committee Approval	ASHRAE BOD Approval	ANSI Approval
a	12, Appendix D, Appendix J	Replaces Table 12-1, modifies language in D2.4 to correspond to updated Table 12-1, and replaces Table J-2.	12/30/14	12/30/14	12/31/14
b	3.1, 10.1, 10.4.2, 10.6.3.2, 10.6.3.3, 10.7.3, 11, C2.1	Adds new definition, adds symbol, modifies language in 10.4.2, clarifies equation in 10.6.3.2, replaces equation in 10.6.3.3, revises 10.7.3 and adds new section 10.7.3.3, adds language to 11.2, revises Figure 11-1d, adds language to C2.1.	6/28/14	7/2/14	7/31/14
с	3.1, 4.6, 5.1. 5.15, 5.16, 10.6.2, 10.6.4	Adds new definition, adds new language to Section 4.6, adds new Sections 5.15 and 5.16, adds new language to Section 10.6.2.5, and corrects numbering in Section 10.6.4.1.	7/1/15	NA	7/28/15
d	4.2.3, 4.3.2, Appendix J	Revises relative humidity language in 4.2.3, 4.3.2, and J10.8.	6/28/14	7/2/14	7/3/14
e	12.5	Adds new Section 12.5.	2/29/16	NA	3/1/16
f	11.3 and . Figure 11-1d	Modifies language in Section 11.3 and makes changes to Figure 11-1d.	2/29/16	NA	3/1/16
g	Appendix K	Adds new Appendix K.	12/30/16	NA	12/30/16
i	13, Appendix G, 6.2	Removes a reference and adds new reference to Section 13, modifies language in Section 6.2, removes footnote 38.	12/30/16	NA	12/30/16

NOTE

Approved addenda, errata, or interpretations for this standard can be downloaded free of charge from the ASHRAE Web site at www.ashrae.org/technology.

INFORMATIVE APPENDIX I
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INFORMATIVE APPENDIX J
OPTIONAL METHOD OF CONDITIONING A
FILTER USING FINE KCL PARTICLES TO
DEMONSTRATE EFFICIENCY LOSS THAT MIGHT
BE REALIZED IN FIELD APPLICATIONS

J1. PURPOSE OF OPTIONAL TEST

Appendix J presents a conditioning procedure to determine the magnitude of the efficiency loss a filter may realize in field applications. This procedure is a separate test from that described in Section 10.7.1.2(b). For any particular type or model of filter, the test described in the body of the standard must be used. If desired, both tests may be used; however, the same test filter may not be tested with both methods. When the test in Appendix J is used, the data output obtained from the efficiency test procedure after the KCl conditioning step is referred to as MERV-A, as defined in Section J2.2. The data output value is thus differentiated from the MERV value that is the data output of the test without the KCl conditioning.

The conditioning step described herein is representative of the best available knowledge of real-life filter efficiency degradation at the time of the publication of this procedure. Changes in filtration performance are environment dependent and, therefore, filters may or may not degrade to the conditioned efficiencies described in this document. For this reason, the results in this appendix may be used to compare filters as described in the foreword to Standard 52.2 (see section titled "Not an Application Standard").

The goal of this appendix is to provide an optional conditioning method of test, gather data using this method, and validate this method to achieve consensus for possible future incorporation into the body of the standard. This procedure is being included as an option to the test method so that those concerned about a possible drop in filtration efficiency have a recognized test method to predict the magnitude of the efficiency loss. This standard is under continuous maintenance, and the committee welcomes continuous maintenance proposals addressing means to improve the method.

J2. DEFINITIONS AND ACRONYMS

J2.1 Definitions to be used in addition to those listed in Section 3 of the standard are as follows:

condensation particle counter (CPC): an instrument used to measure the concentration of submicrometer aerosol particles. Also called a *condensation nucleus counter (CNC)*.

conditioning aerosol: a submicrometer solid-phase potassium chloride aerosol used to reproduce the falloff in efficiency that electret filters may experience in real-life applications.

CT: for the conditioning aerosol, the product of the in-duct aerosol concentration C measured with the CPC and the exposure time T.

Laskin generator: a nozzle that uses a source of compressed air as part of a system to generate a polydispersed aerosol from a liquid. Note: A Laskin generator is shown in NSF Standard 49: Class II (Laminar Flow) Biosafety Cabinetry.

J2.2 Acronyms to be used in addition to those listed in Section 3 of the standard are as follows:

A_{avg}-A = average value of the arrestances made on the device during loading test when Appendix J conditioning is used.

DHC-A = the total weight of the synthetic loading dust captured when Appendix J conditioning is used.

MERV-A #-A = minimum efficiency reporting value according to Appendix J, where # represents the numeric value from Table J-2.

J3. TEST APPARATUS FOR CONDITIONING AEROSOL IN ADDITION TO THE TEST APPARATUS REQUIRED IN SECTION 4, "TEST APPARATUS"

J3.1 Condensation Particle Counter. The in-duct concentration of the conditioning aerosol shall be measured with a CPC having a minimum 50% counting efficiency at 0.02 μ m. The CPC shall have a concentration limit of \geq 500,000 cm⁻³. The CPC shall not be operated above its concentration limit.

J3.2 Laskin Generator. The conditioning aerosol shall be generated using one or more Laskin generators. The aerosol output of the Laskin generators is not required to be passed through a charge neutralizer. The nozzles shall be operated at air pressures of 20 to 60 psig. The Laskin generators shall be operated with an aqueous solution of KCl in water prepared to a ratio of 1.00 g of reagent grade KCl for each 1.00 L of distilled or filtered deionized water. The compressed air line supplying the Laskin generator shall be equipped with devices for the removal of oil and water and have a high-efficiency particle filter (99.97% @ 0.3 μm or better) installed near the Laskin generators. The conditioning aerosol shall be injected between the inlet filter bank (item 3 of Figure 4-1) and the upstream mixing orifice (item 9 of Figure 4-1).

J3.3 Separate Duct for Conditioning Step. The use of a separate duct for the conditioning portion of the test is acceptable as long as the conditioning duct meets the following criteria:

- a. The cross-sectional dimensions of the duct are 610 \times 610 mm (24 \times 24 in.).
- b. The HEPA filter bank, transition, aerosol injection tube, mixing orifice, perforated diffusion plate, upstream sampling probe, and main flow measurement nozzle are designed and installed according to Section 4.2.
- The test filter does not extend beyond the length of the duct.
- d. Test environmental conditions meet Section 4.2.3.

The conditioning duct can be operated in a positive or a negative pressure mode.

J4. SUBSECTION TO BE USED WITH SECTION 5.1

J4.1 If a separate duct is used for the conditioning step (see Section J3.3) then velocity uniformity (see Section 5.2) shall be performed on that duct.

J5. SUBSECTION TO BE USED WITH SECTION 5, "APPARATUS QUALIFICATION TESTING"

J5.1 Uniformity of the Conditioning Aerosol Concentration

- J5.1.1 The uniformity of the conditioning aerosol concentration across the duct cross section shall be determined by a nine-point traverse in the 610 × 610 mm (24 × 24 in.) duct immediately upstream of the device section (i.e., at the location of the upstream sample probe) using the grid points shown in Figure 5-1. The traverse shall be made by either (a) installing nine sample probes of identical curvature, diameter, and inlet nozzle diameter but of variable vertical length or (b) repositioning a single probe.
- **J5.1.2** The conditioning aerosol generation system shall be operated in the same manner as intended for conditioning of test filters.
- J5.1.3 The aerosol concentration measurements shall be made with a CPC meeting the specifications of Section J3.1. A one-minute average concentration shall be recorded at each grid point. The average shall be based on at least ten readings

taken at equal intervals during the one-minute period. After sampling all nine points, the traverse shall then be repeated four more times to provide a total of five samples from each point. These five values for each point shall then be averaged. The traverse measurements shall be performed at airflow rates of 0.22, 0.93, and 1.4 m³/s (472, 1970, and 2990 cfm).

- **J5.2** The CV of the corresponding nine grid point particle concentrations shall be less than 15% for each airflow rate.
- J5.2.1 Ratio of Small to Large Particles in the Conditioning Aerosol. With the conditioning aerosol generator operating as it would for conditioning operation during a standard test, the in-duct aerosol concentration shall be measured with the CPC and with the particle counter used for PSE testing. The CPC sample inlet shall be located within 100 mm (4 in.) of the OPS inlet, and they can share the same inlet. The ratio of the CPC concentration to the concentration of particles $>0.3~\mu m$ (measured by the PSE particle counter and consisting of all particles measured between 0.3 and 10 μm) shall be >20,000.

Note: The units of concentration must be the same to calculate the correct ratio. Typically the particle counter output is in units of particles/m³ and the CPC output is in units of particles/cm³.

J6. SUBSECTION TO BE USED WITH TABLE 5-1, SYSTEM QUALIFICATION MEASUREMENT REQUIREMENTS OF THE STANDARD

2.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1	n
Parameter	Requirement
Ratio of the CPC concentration to the concentration of particles >0.3 μ m (measured by the PSE particle counter)	Ratio > 20,000
Conditioning aerosol uniformity: based on traverse measurements made over a 9-point equal- area grid at each test airflow rate	CV < 15%
Conditioning aerosol in-duct aerosol concentration	$<1 \times 10^6$ cm ⁻³ or less than the concentration limit of the CPC, whichever is smaller

J7. SUBSECTION TO BE USED WITH TABLE 5-2, APPARATUS MAINTENANCE SCHEDULE OF THE STANDARD

Maintenance Item	Incorporated into Each Test	Monthly	Biannually	After Change that May Alter Performance	Comment
Drain, rinse, and refill the Laskin generator with fresh 0.1% KCl solution					Daily
Ratio of the CPC concentration to the concentration of particles >0.3 µm	×				
Conditioning aerosol uniformity			×	×	
Conditioning aerosol concentration	×				

J8. SUBSECTION TO BE USED WITH SECTION 6, "TEST MATERIALS"

J8.1 Conditioning Aerosol. The conditioning aerosol shall be solid-phase potassium chloride (KCl) particles generated from an aqueous solution. The solution shall be prepared by dissolving reagent-grade KCl in distilled or filtered deionized water at a proportion of 1.00 g of KCl per 1.00 L of water.

J9. SUBSECTION TO BE USED WITH SECTION 8.2, "TEST SEQUENCE"

J9.1 Test Sequence. The sequence of tests on the device shall be as follows:

- Resistance vs. airflow rate of the clean device at various airflow rates as prescribed in Section 9.
- b. PSE of the clean device as prescribed in Section 10.
- PSE of the device, as prescribed in Section 10, after conditioning per this appendix.
- d. PSE of the device, as prescribed in Section 10, when incrementally loaded with synthetic dust, with the exception of the 30 g conditioning load (see Section 10.7.1.2.b).

J10. CONDITIONING PROCEDURE (USE THIS PROCEDURE INSTEAD OF SECTION 10.7.1.2.B OF THE STANDARD)

J10.1 After the initial efficiency test is completed, the filter shall be exposed to the conditioning aerosol. The duct airflow rate used during the conditioning step will be the same as is used during the dust-loading and particle size efficiency testing. Note that all filters tested according to this standard must be exposed to the same conditioning aerosol procedure, regardless of the specific materials, construction details, or other variables.

J10.2 Prior to conditioning, all internal surfaces of the Laskin generator shall be rinsed with distilled or filtered deionized water and then filled with KCl solution, as specified in Section J8.1.

J10.3 Record the background concentration using the CPC upstream of the test device with the duct airflow rate set to the same value used during testing.

J10.4 The measured in-duct conditioning aerosol concentration shall not exceed 1.0×10^6 particles/cm³.

J10.5 Conditioning shall be performed in incremental steps with a PSE taken after each increment. The minimum incremental conditioning step shall be a CT of 6.4×10^7 particles/cm³·min. Conditioning is stopped when either (a) the current measurement shows no further significant drop in efficiency or (b) the cumulative CT exposure of the filter reaches a CT of 1.2×10^9 particles/cm³·min. A "significant drop" is a drop in efficiency of at least two percentage points in two or more adjacent particle size ranges relative to the minimum efficiencies in those ranges measured in any of the previous steps.

Note: Filters with large media area (typical of 300 mm or 12 in. filters and bag filters) may require cumulative conditioning CTs up to the maximum level of 1.2×10^9 particles/cm³· min. The test laboratory should select an incremental conditioning step size consistent with this expectation and avoid relatively

small conditioning increments that may underchallenge the filter.

J10.6 Periodically during conditioning, the in-duct concentration of the conditioning aerosol shall be measured and recorded. The measurement interval shall be such that a minimum of three measurements are obtained during each conditioning interval.

J10.7 Whenever the determined correlation ratio is (see Section 10.3), it is recommended that the ratio of the concentration of small to large particles be measured. This ratio must be evaluated a minimum of two times during the conditioning procedure, once at the beginning of the conditioning and once at the end of the conditioning. The small-particle concentration is that obtained from the CPC. The large-particle concentration is that obtained from the PSE particle counter and is the concentration of all particles >0.3 μ m. The ratio of the concentrations must be >20,000.

J10.8 To prevent deliquescence of the KCl during conditioning, relative humidity must be maintained below 50% in the test duct at all times during the test. Also, the airflow from all particle generators must result in relative humidity \leq 50% in the air in the rig at all times after mixing has occurred. If the filter is removed from the test duct for any reason during the test, it must be stored in an environment with relative humidity less than 65%.

J11. SUBSECTION TO BE USED WITH SECTION 11.2

J11.1 Conditioning

- a. The background concentration (particles/cm³)
- The average conditioning aerosol concentration (particles/cm³)
- c. The cumulative conditioning duration (minutes)
- d. The cumulative conditioning CT (particles/cm³ min)
- e. The PSE following each conditioning increment
- f. Dust holding capacity DHC-A (grams)

J11.2 Minimum Efficiency Reporting Value (MERV-A) According to Appendix J

- a. The average of the minimum PSE of the four size ranges from 0.30 to 1.0 μm (E₁-A)
- b. The average of the minimum PSE of the four size ranges from 1.0 to 3.0 μ m (E_2 -A)
- The average of the minimum PSE of the four size ranges from 3.0 to 10.0 μm (E₃-A)
- d. MERV-A for the device

J11.3 Minimum Efficiency Reporting Value (MERV-A) According to Appendix J for Air Cleaners

J11.3.1 The minimum efficiency reporting value (MERV-A) for an air cleaner shall be based on three composite average PSE points developed from a test at a manufacturer's specified airflow rate selected in accordance with Section 8.1. Dust loading shall follow the procedure outlined in Section 10.7 except substituting Section J10 of this appendix for Section 10.7.1.2(b) of the standard. The results of the tests shall be reported in accordance with Sections 10.8.1 and 10.8.2. The four data points from the Section 10.8.2 composite curve in each of the three size range groups from

Table J-1 shall be averaged and the resultant three average minimum PSEs (E_1 -A, E_2 -A, and E_3 -A) shall be reported.

J11.3.2 With this appendix, the minimum final resistance for an air cleaner shall always be the same as or greater than twice the initial resistance.

J11.3.3 With this appendix, the minimum efficiency reporting value in the specified size ranges for reporting purposes shall be in accordance with Table J-2.

J11.3.4 The reporting designator shall be a combination of the air cleaner's MERV-A and the test airflow rate (e.g., MERV-A 10-A at 0.93 indicates that the air cleaner has a

Table J-1 Size Range Groups

Average Minimum PSE Designator	Corresponding Size Range Group, μm
E ₁ -A	0.30 to 1.0
E ₂ -A	1.0 to 3.0
E ₃ -A	3.0 to 10

Table J-2 KCI Conditioned Per Appendix J Minimum Efficiency Reporting Value (MERV-A) Parameters

Standard 52.2	Composite Average l				
Minimum Efficiency Reporting Value (MERV-A)	Range 1 (0.30 to 1.0 μm)	Range 2 (1.0 to 3.0 μm)	Range 3 (3.0 to 10.0 μm)	Average Arrestance, %	
1-A	N/A	N/A	E_3 -A < 20	A _{avg} < 65	
2-A	N/A	N/A	E_3 -A < 20	$65 \le A_{avg}$	
3-A	N/A	N/A	E_3 -A < 20	$70 \le A_{avg}$	
4-A	N/A	N/A	E_3 -A < 20	$75 \le A_{avg}$	
5-A	N/A	N/A	$20 \le E_3$ -A	N/A	
6-A	N/A	N/A	$35 \le E_3$ -A	N/A	
7-A	N/A	N/A	$50 \le E_3$ -A	N/A	
8-A	N/A	$20 \le E_2$ -A	$70 \le E_3$ -A	N/A	
9-A	N/A	$35 \le E_2$ -A	$75 \le E_3$ -A	N/A	
10-A	N/A	$50 \le E_2$ -A	$80 \le E_3$ -A	N/A	
11-A	$20 \le E_1$ -A	$65 \le E_2$ -A	$85 \le E_3$ -A	N/A	
12-A	$35 \le E_1$ -A	$80 \le E_2$ -A	$90 \le E_3$ -A	N/A	
13-A	$50 \le E_1$ -A	$85 \le E_2$ -A	90 ≤ E_3 -A	N/A	
14-A	$75 \le E_1$ -A	$90 \le E_2$ -A	$95 \le E_3$ -A	N/A	
15-A	$85 \le E_1$ -A	$90 \le E_2$ -A	95 ≤ E_3 -A	N/A	
16-A	$95 \le E_1$ -A	$95 \le E_2$ -A	95 ≤ E_3 -A	N/A	

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ASHRAE Standard 52.2 Air-Cleaner Performance Report Summary with Optional Conditioning Procedure According to Appendix J

(This report applies to the tested device only)

Donart number		
Keport number	Test number	Date
Test laboratory		
	Supervisor	
Particle counters: Brand		odel
Device Manufacturer's Da		
Manufacturer	Product r	name
	Test requested by	
		itial pressure drop
	Airflow Fi	nal pressure drop
race velocity		
Device Description		
	Width	Depth
Generic name		e
Effective media area		color
Amount and type of adhesiv	ve (Tackifier)	
T C 1111		
Test Conditions	T	Dalatha Hamilda
Test cornect to the	Final pressure drop	Relative Humidity
		Face velocity
	two ducts used).	
Duct configuration (one or		
	two ducts used).	
Remarks		
Remarks Conditioning Parameters		
Remarks Conditioning Parameters Background concentration ((particles/cm ³)	
Remarks Conditioning Parameters Background concentration (Average cond aerosol conce	(particles/cm ³) entration (particles/cm ³)	
Remarks Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du	(particles/cm ³) entration (particles/cm ³) uration (minutes)	
Remarks Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit	(particles/cm ³) entration (particles/cm ³) uration (minutes) tioned in the same duct?	
Remarks Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit Cumulative conditioning C	(particles/cm ³) entration (particles/cm ³) eration (minutes) tioned in the same duct? T (particles/cm ³ min)	
Remarks Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit	(particles/cm ³) entration (particles/cm ³) eration (minutes) tioned in the same duct? T (particles/cm ³ min)	
Remarks Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit Cumulative conditioning C' PSE following each conditioning	(particles/cm ³) entration (particles/cm ³) eration (minutes) tioned in the same duct? T (particles/cm ³ min)	
Remarks Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit Cumulative conditioning C	(particles/cm ³) entration (particles/cm ³) eration (minutes) tioned in the same duct? T (particles/cm ³ min)	
Remarks Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit Cumulative conditioning C' PSE following each condition Resistance Test Results	(particles/cm ³) entration (particles/cm ³) tration (minutes) tioned in the same duct? T (particles/cm ³ min) oning increment	
Remarks Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit Cumulative conditioning C' PSE following each condition Resistance Test Results	(particles/cm ³) entration (particles/cm ³) eration (minutes) tioned in the same duct? T (particles/cm ³ min)	
Remarks Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit Cumulative conditioning C' PSE following each condition Resistance Test Results Initial resistance	(particles/cm ³) entration (particles/cm ³) tration (minutes) tioned in the same duct? T (particles/cm ³ min) oning increment	tance_
Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit Cumulative conditioning C' PSE following each condition Resistance Test Results Initial resistance KCl Conditioned Minimu	(particles/cm³) entration (particles/cm³) uration (minutes) tioned in the same duct? T (particles/cm³ min) oning increment Final resis	tance(According to Appendix J)
Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit Cumulative conditioning C' PSE following each condition Resistance Test Results Initial resistance KCI Conditioned Minimu Composite average efficience	(particles/cm 3) entration (particles/cm 3) ration (minutes) tioned in the same duct? T (particles/cm 3 min) oning increment Final resis m Efficiency Reporting Data (cies: E_1 -A E_2 -	tance(According to Appendix J)
Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit Cumulative conditioning C' PSE following each condition Resistance Test Results Initial resistance KCI Conditioned Minimu Composite average efficience	(particles/cm 3) entration (particles/cm 3) ration (minutes) tioned in the same duct? T (particles/cm 3 min) oning increment Final resis m Efficiency Reporting Data (cies: E_1 -A E_2 -	tance_
Conditioning Parameters Background concentration (Average cond aerosol conce Cumulative conditioning du Is filter continuously condit Cumulative conditioning C' PSE following each condition Resistance Test Results Initial resistance KCI Conditioned Minimu Composite average efficience	(particles/cm³) entration (particles/cm³) uration (minutes) tioned in the same duct? T (particles/cm³ min) oning increment Final resis m Efficiency Reporting Data of the cies: E1-A E2-mance: Aavg-A	tance(According to Appendix J)

(This appendix is not part of this standard. It is merely informative and does not contain requirements necessary for conformance to the standard. It has not been processed according to the ANSI requirements for a standard and has not been subject to public review or a consensus process. Unresolved objectors on informative material are not offered the right to appeal at ASHRAE or ANSI.)

INFORMATIVE APPENDIX K
OPTIONAL METHOD OF TESTING
TWO AIR FILTERS ARRANGED IN SERIES IN A
SYSTEM TO EVALUATE PARTICLE REMOVAL,
DUST LOADING, AND PRESSURE DROP INCREASE
THAT MIGHT BE REALIZED IN
FIELD APPLICATIONS

K1. PURPOSE OF OPTIONAL TEST

This appendix is to be used to evaluate the performance of two air-cleaning devices arranged in airflow series. In this appendix the first filter serves as a prefilter and the second filter serves as the final filter. It is possible for both filters to be the same filter. The test protocol is based on ASHRAE Standard 52.2. Equipment and procedures specified in Standard 52.2 are used to conduct this test.

This procedure measures the ability of the prefilter and final filter to remove dust as the filters become loaded with a standardized loading dust. The loading dust is fed at intervals to simulate accumulation of particles during filter service life. Resistances of the individual filters are monitored separately. The prefilter is replaced with a new prefilter whenever its preselected final resistance is reached. This process is continued until the preselected resistance of the final filter is reached. After the initial particle size efficiency (PSE) test, the resistance of the final filter is used to position the five additional PSE tests.

K2. DEFINITIONS AND ACRONYMS

K2.1 Definitions to be used in addition to those listed in Section 3 of Standard 52.2 are as follows.

dust-holding capacity final filter (DHCFF): the total weight of the synthetic loading dust captured by the second-in-series air-cleaning device over the dust-loading steps until the final filter reaches it predetermined final resistance.

dust-holding capacity prefilter #1 (DHCPF1): the total weight of the synthetic loading dust captured by the first-inseries air-cleaning device over the dust-loading steps until the prefilter reaches its predetermined final resistance. Each additional prefilter designation would be the next incremental numerical digit, i.e., DHCPF2, DHCPF3.

final filter: the second filter in the two-stage system.

prefilter: the first filter in the two-stage system.

total system dust-holding capacity (TDHC): the sum total weight of the synthetic loading of all prefilters and the final filter.

K3. SUBSECTION TO BE USED WITH SECTION 7.2, "PREPARATION OF THE SAMPLES"

K3.1 The devices shall be installed in the duct with a space between the filters of 203 to 914 mm (8 to 36 in.).

K3.2 Distance between devices should be documented in the test report.

K4. SUBSECTION TO BE USED WITH SECTION 8.2, "TEST PROCEDURES"

K4.1 Test Sequence. The sequence of tests on the two-stage system shall be as follows:

- Resistance vs. airflow rate of the prefilter at various airflow rates as prescribed in Section 9.
- b. Resistance vs. airflow rate of the final filter at various airflow rates as prescribed in Section 9.
- c. PSE prescribed in Section 10.7.1.2(b) to be replaced with the following: The prefilter after an initial conditioning step with a dust loading of 30 g or an increase of 10 Pa (0.04 in. of water) pressure drop across the prefilter, whichever comes first.
- d. PSE prescribed in Section 10.7.1.2(c) to be replaced with the following: After the dust-loading increments have achieved an airflow resistance increase of one-quarter, one-half, and three-quarters of the difference between the beginning and the prescribed end-point limit of airflow resistance for the final filter.
- e. PSE prescribed in Section 10.7.1.2(d) to be replaced with the following: After the dust increment that loads the final filter to its prescribed end point resistance limit.

K5. SUBSECTION TO BE USED WITH SECTION 9, "MEASUREMENT OF RESISTANCE VERSUS AIRFLOW"

K5.1 Measure, record, and report the resistance of the prefilter, the final filter, and the system at a minimum of four airflow rates: 50%, 75%, 100%, and 125% of test airflow rate. Resistance shall be measured between the static taps.

K6. SUBSECTION TO BE USED WITH SECTION 10.7.2, "DUST LOADING PROCEDURES"

K6.1 When the prefilter reaches its prescribed final resistance, it shall be replaced by a clean prefilter. The replacement filter shall be identical to the one being replaced.

K6.2 Repeat the prefilter replacement process until the final filter reaches its final resistance.

K6.3 Weigh each prefilter to the nearest 0.1 g before and after use to determine dust weight gain (DWG).

K6.4 Weigh final filter to the nearest 0.1 g before and after use to determine DWG.

K7. SUBSECTION TO BE USED WITH SECTION 10.8, "REPORTING RESULTS OF LOADING TESTS"

K7.1 Results of loading tests shall be reported in the form of PSE curves for the two-stage system:

CASE 0:15-md-02666-JNE-DTS Doc. 810-1 Filed 09/12/17 Page 258 of 269

- a. clean;
- after each incremental dust loading of the final filter, a total of four curves; and
- c. at final filters final loading point.

K8. SUBSECTION TO BE USED WITH SECTION 11, "REPORTING RESULTS"

K8.1 The summary section of the performance report shall include the following information.

- a. Name and location of the test laboratory
- b. Date of the test
- c. Test operator's names
- d. Brand and model number of the particle counting and sizing devices
- e. Air-cleaner manufacturer's name (or name of the marketing organization if different from the manufacturer)
- f. How the sample was obtained
- g. Description of each test air cleaner, including the following:
 - 1. Brand and model number
 - Physical description of construction (e.g., extended surface—number of pockets or number of pleats; pleated panel—number and depth of pleats)
 - 3. Face dimensions and depth
 - 4. For fiber media air cleaners
 - i. Type and color of media
 - ii. Effective media area
 - iii. Type and amount of dust adhesive if known
 - iv. Electrostatic charge if known
 - 5. Any other pertinent descriptive attributes
- h. Operating data as stated by the manufacturer
 - 1. Test conditions for reporting purposes: airflow rate
 - 2. Final resistances for both air cleaners

- 3. Any other operating data furnished
- i. Test data
 - 1. Test air temperature and relative humidity
 - 2. Airflow rate
 - 3. Type of test aerosol
 - Distance between the two filters from back edge of prefilter to front edge of final filter
- j. Results of resistance testing
 - 1. Initial resistance of prefilter
 - 2. Initial resistance of final filter
 - 3. Initial resistance of system
 - 4. Final resistance of system
 - 5. Number of times the prefilter is changed
- k. Performance curves
 - A curve in Figure 11-1b format of the prefilter, final filter, and system resistance when clean vs. airflow rates from 50% to 125% of test flow
 - A curve in Figure 11-1c format of PSE for the clean system and for the system at each of the five loading stages of the final filter
 - A minimum PSE composite curve in Figure 11-1c format whose data points are the lowest PSEs from the six measurements in each particle size range from the curves of test results for the system
 - Resistance vs. synthetic loading dust fed during the entire test sequence for prefilter, final filter, and system
- 1. Average ASHRAE dust arrestance
- m. Dust holding capacity (DHC)
 - 1. A DHC for each prefilter
 - 2. A DHC for the final filter
 - 3. A DHC for the entire test cycle

NOTICE

INSTRUCTIONS FOR SUBMITTING A PROPOSED CHANGE TO THIS STANDARD UNDER CONTINUOUS MAINTENANCE

This standard is maintained under continuous maintenance procedures by a Standard Project Committee (SSPC) for which the Standards Committee has established a documented program for regular publication of addenda or revisions, including procedures for timely, documented, consensus action on requests for change to any part of the standard. SSPC consideration will be given to proposed changes within 13 months of receipt by the Senior Manager of Standards (SMOS).

Proposed changes must be submitted to the SMOS in the latest published format available from the SMOS. However, the SMOS may accept proposed changes in an earlier published format if the SM`OS concludes that the differences are immaterial to the proposed change submittal. If the SMOS concludes that a current form must be utilized, the proposer may be given up to 20 additional days to resubmit the proposed changes in the current format.

ELECTRONIC PREPARATION/SUBMISSION OF FORM FOR PROPOSING CHANGES

An electronic version of each change, which must comply with the instructions in the Notice and the Form, is the preferred form of submittal to ASHRAE Headquarters at the address shown below. The electronic format facilitates both paper-based and computer-based processing. Submittal in paper form is acceptable. The following instructions apply to change proposals submitted in electronic form.

Use the appropriate file format for your word processor and save the file in either a recent version of Microsoft Word (preferred) or another commonly used word-processing program. Please save each change proposal file with a different name (for example, "prop01.doc," "prop02.doc," etc.). If supplemental background documents to support changes submitted are included, it is preferred that they also be in electronic form as word-processed or scanned documents.

For files submitted attached to an e-mail, ASHRAE will accept an electronic signature (as a picture; *.tif, or *.wpg) on the change submittal form as equivalent to the signature required on the change submittal form to convey non-exclusive copyright.

Submit an e-mail containing the change proposal files to: change.proposal@ashrae.org

Alternatively, mail paper versions to:

ASHRAE Senior Manager of Standards 1791 Tullie Circle, NE Atlanta, GA 30329-2305

Or fax them to:

Attn: Senior Manager of Standards 678-539-2129

The form and instructions for electronic submittal may be obtained from the Standards section of ASHRAE's Home Page, www.ashrae.org, or by contacting a Standards Secretary via phone (404-636-8400), fax (678-539-2129), e-mail (standards.section@ashrae.org), or mail (1791 Tullie Circle, NE, Atlanta, GA 30329-2305).



FORM FOR SUBMITTAL OF PROPOSED CHANGE TO AN ASHRAE STANDARD UNDER CONTINUOUS MAINTENANCE

NOTE: Use a separate form for each comment. Submittals (Microsoft Word preferred) may be attached to e-mail (preferred), or submitted in paper by mail or fax to ASHRAE, Senior Manager of Standards, 1791 Tullie Circle, NE, Atlanta, GA 30329-2305. E-mail: change.proposal@ashrae.org. Fax: +1-678-539-2129.

1. Submitter:					
Affiliation:					
Address:		City:	State:	Zip:	Country:
Telephone:	Fax:		E-Mail:		
understand that I acquir	E the non-exclusive roya te no rights in publication we the authority and am	n of the standard in	which my proposa	als in this or o	right, in my proposals. I other analogous form is used.
Submitter's signature:			Date	:	
All electronic submitte	als must have the follow	ring statement con	npleted:		
I (insert name)			through	h this alastus	nic signature, hereby grant
acquire no rights in puthat I have the authorit 2. Number and year o 3. Page number and c 4. I propose to: (check one)	blication of the standard y and am empowered to	in which my prop grant this copyrig use, or paragraph and as follows t as follows	number: [] Delete a	and substitute	itution
6. Reason and substan	itiation:				
7. Will the proposed contour to why the increase is		of engineering o	r construction? If	yes, provide	a brief explanation as
[] Check if attachmen		als cited in this pro	posal accompany the		change. Please verify that all view delays. Please list your

POLICY STATEMENT DEFINING ASHRAE'S CONCERN FOR THE ENVIRONMENTAL IMPACT OF ITS ACTIVITIES

ASHRAE is concerned with the impact of its members' activities on both the indoor and outdoor environment. ASHRAE's members will strive to minimize any possible deleterious effect on the indoor and outdoor environment of the systems and components in their responsibility while maximizing the beneficial effects these systems provide, consistent with accepted Standards and the practical state of the art.

ASHRAE's short-range goal is to ensure that the systems and components within its scope do not impact the indoor and outdoor environment to a greater extent than specified by the Standards and Guidelines as established by itself and other responsible bodies.

As an ongoing goal, ASHRAE will, through its Standards Committee and extensive Technical Committee structure, continue to generate up-to-date Standards and Guidelines where appropriate and adopt, recommend, and promote those new and revised Standards developed by other responsible organizations.

Through its *Handbook*, appropriate chapters will contain up-to-date Standards and design considerations as the material is systematically revised.

ASHRAE will take the lead with respect to dissemination of environmental information of its primary interest and will seek out and disseminate information from other responsible organizations that is pertinent, as guides to updating Standards and Guidelines.

The effects of the design and selection of equipment and systems will be considered within the scope of the system's intended use and expected misuse. The disposal of hazardous materials, if any, will also be considered.

ASHRAE's primary concern for environmental impact will be at the site where equipment within ASHRAE's scope operates. However, energy source selection and the possible environmental impact due to the energy source and energy transportation will be considered where possible. Recommendations concerning energy source selection should be made by its members.

ASHRAE · 1791 Tullie Circle NE · Atlanta, GA 30329 · www.ashrae.org

About ASHRAE

ASHRAE, founded in 1894, is a global society advancing human well-being through sustainable technology for the built environment. The Society and its members focus on building systems, energy efficiency, indoor air quality, refrigeration, and sustainability. Through research, Standards writing, publishing, certification and continuing education, ASHRAE shapes tomorrow's built environment today.

For more information or to become a member of ASHRAE, visit www.ashrae.org.

To stay current with this and other ASHRAE Standards and Guidelines, visit www.ashrae.org/standards.

Visit the ASHRAE Bookstore

ASHRAE offers its Standards and Guidelines in print, as immediately downloadable PDFs, on CD-ROM, and via ASHRAE Digital Collections, which provides online access with automatic updates as well as historical versions of publications. Selected Standards and Guidelines are also offered in redline versions that indicate the changes made between the active Standard or Guideline and its previous version. For more information, visit the Standards and Guidelines section of the ASHRAE Bookstore at www.ashrae.org/bookstore.

IMPORTANT NOTICES ABOUT THIS STANDARD

To ensure that you have all of the approved addenda, errata, and interpretations for this Standard, visit www.ashrae.org/standards to download them free of charge.

Addenda, errata, and interpretations for ASHRAE Standards and Guidelines are no longer distributed with copies of the Standards and Guidelines. ASHRAE provides these addenda, errata, and interpretations only in electronic form to promote more sustainable use of resources.

Product code: 86178 2/17

EXHIBIT DX44

TO DECLARATION OF PETER J. GOSS IN
SUPPORT OF DEFENDANTS' MOTION TO
EXCLUDE PLAINTIFFS' ENGINEERING
EXPERTS



LMS TECHNOLOGIES, INC.

6423 Cecilia Circle Bloomington, MN 55439 (952) 918-9060, Fax: (952) 918-9061

Test Report-ASHRAE Test Standard 52.2-2012 (New Classification)

Report #: 3461

Test Requested By:

Manufacturer:

3M

Test Date: 05/10/2016

Product Name:

Bair Hugger Filter - Model 505 # 1 4693367

Lot #: Part #:

78-8083-5447-2

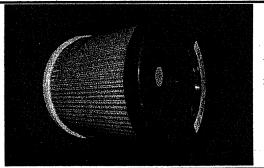
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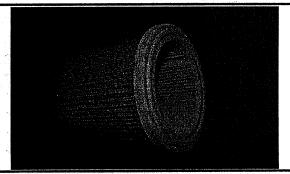
5.5" x 5.375"

Filter Description:

Mini Pleated Cylindrical Filter with White Media

How Filter Obtained: Provided by 3M





Test Results

Test Air Flow Rate(CFM)/Velocity (FPM)

Initial Resistance (in. WG)

Final Resistance (in. WG)

Minimum Efficiency Rating Value (MERV)

Minimum Average Efficiency 0.3 to 1.0 Microns (E1)

Minimum Average Efficiency 1.0 to 3.0 Microns (E2)

Minimum Average Efficiency 3.0 to 10 Microns (E3)

Dust Fed to Final Resistance (grams)

Dust Holding Capacity (grams)

Arrestance:

48 cfm/	1	18	f	pm
0.508"		-		

2.500"

MERV 14 @ 48 cfm

81.5

98.7

100.0 6.1 grams

6.0 grams

98.4%

Test Description

Temp & Humidity:

71° F @ 40%

Particle Analysis:

Met One 3400

Test Dust: Test Aerosol: **ASHRAE 52.1 Dust**

LMS#:

KCl, Neutralized 3894

Test Engineer:

Emile Tadros/Kevin Kwong/Pat Best/Jose Tizcareno

Approved By:

K. C. Kwok, Ph.D.

Data verified by LMS Calibration filter* Patent Pending



LMS Technologies, Inc. 6423 Cecilia Circle Bloomington, MN 55439

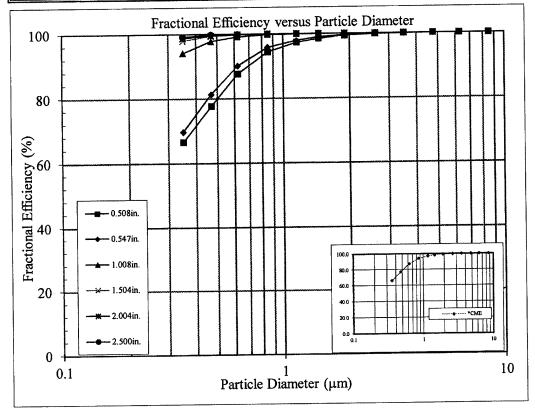
(952) 918-9060, Fax: (952) 918-9061 Requested by: May 10, 2016

Bair Hugger-Model 505 #1 3M Filter ID:

Date:

Manufacturer: 52.2-2012 **REP# 3461** Test Type: 3M Test Aerosol: KCl, Neutralized

ΔP (" H ₂ O)	0.508in.	0.547in.	1.008in.	1.504in.	2.004in.	2.500in.	*CME
Size Range (µm)			Fractio	nal Efficie	ncy (%)		
0.3-0.4	66.5	69.7	94.1	97.9	98.7	99.1	66.5
0.4-0.55	77.6	81.3	97.7	99.3	99.5	99.8	77.6
0.55-0.7	87.6	90.1	99.1	99.7	99.8	99.9	87.6
0.7-1.0	94.3	95.8	99.7	99.9	100.0	100.0	94.3
1.0-1.3	97.2	97.8	99.9	100.0	100.0	100.0	97.2
1.3-1.6	98.4	98.9	99.9	100.0	100.0	100.0	98.4
1.6-2.2	99.3	99.5	100.0	100.0	100.0	100.0	99.3
2.2-3.0	99.7	99.8	100.0	100.0	100.0	100.0	99.7
3.0-4.0	99.9	99.9	100.0	100.0	100.0	100.0	99.9
4.0-5.5	100.0	100.0	100.0	100.0	100.0	100.0	100.0
5.5-7.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
7.0-10.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0



ENGINEERING APPROVAL K.C. KWOK, PH.D.____

LMS Technologies, Inc. 6423 Cecilia Circle, Bloomington, MN 55439 (952) 918-9060, Fax: (952) 918-9061

Date:

May 10, 2016

Test Requested by:

Filter ID:

Bair Hugger Filter-Model 505 #1

3M

Test Type:

Pressure Drop of Clean Filter

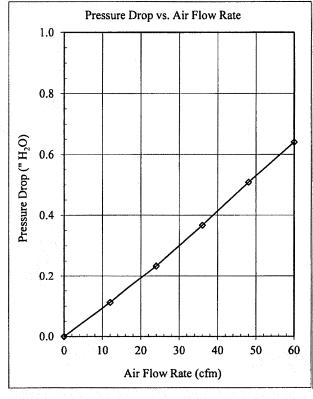
Filter Manufacturer:

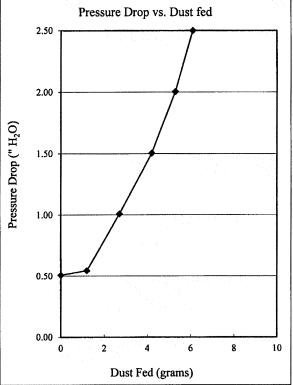
For ASHRAE **52.2-2012**

13M

Flow Rate CFM	Velocity FPM	dP (mm H2O)	Pressure drop ("H2O)	% of Rated Airflow	Dust fed	Pressure drop
0	0	0.00	0.000	0%	0.00	0.508
12	30	2.86	0.113	25%	1.20	0.547
24	59	5.95	0.234	50%	2.70	1.008
36	89	9.33	0.367	75%	4.20	1.504
48	118	12.92	0.509	100%	5.30	2.004
60	148	16.27	0.641	125%	6.10	2.500

REP# 3461





ENGINEERING APPROVAL K.C.KWOK PH.D.___



LMS TECHNOLOGIES, INC.

6423 Cecilia Circle Bloomington, MN 55439 (952) 918-9060, Fax: (952) 918-9061

Test Report-ASHRAE Test Standard 52.2-2012 (New Classification)

Report #: 3463

Test Requested By:

3M

Manufacturer:

3M

Test Date: 05/12/2016

Product Name:

Bair Hugger Filter - 700 Series #1 4693352

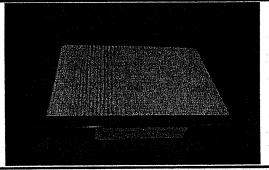
Lot #: Part #:

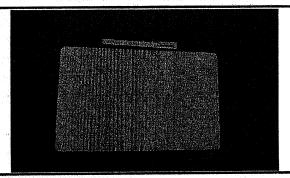
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Dimensions: Filter Description: 4.75" x 6.625" x 0.75"

How Filter Obtained:

Mini Pleated Filter with White Media Provided by 3M





Test Results

Test Air Flow Rate(CFM)/Velocity (FPM)

Initial Resistance (in. WG)

Final Resistance (in. WG)

Minimum Efficiency Rating Value (MERV)

Minimum Average Efficiency 0.3 to 1.0 Microns (E1)

Minimum Average Efficiency 1.0 to 3.0 Microns (E2)

Minimum Average Efficiency 3.0 to 10 Microns (E3)

Dust Fed to Final Resistance (grams)

Dust Holding Capacity (grams)

Arrestance:

48 cfm	/246	fpm	
1.256"	200	7.00	

2.500"

MERV 14 @ 48 cfm

84.1

99.4

100.0 1.1 grams

1.1 grams

100.0%

Test Description

Temp & Humidity:

71° F @ 40%

Particle Analysis:

Met One 3400

Test Dust:

ASHRAE 52.1 Dust

Test Aerosol: LMS#:

KCl, Neutralized 3894

Test Engineer:

Emile Tadros/Kevin Kwong/Pat Best/Jose Tizcareno

Approved By:

K. C. Kwok, Ph.D.

Data verified by LMS Calibration filter* Patent Pending



LMS Technologies, Inc.

6423 Cecilia Circle

Bloomington, MN 55439 (952) 918-9060, Fax: (952) 918-9061

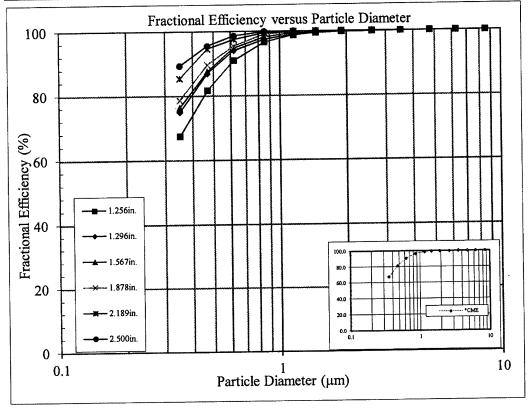
Date: May 12, 2016 Requested by:

Filter ID: Bair Hugger-700 Series #1 3M

Test Type: 52.2-2012 REP# 3463 Manufacturer:

Test Aerosol: KCl, Neutralized 3M

ΔP (" H ₂ O)	1.256in.	1.296in.	1.567in.	1.878in.	2.189in.	2.500in.	*CME
Size Range (µm)			Fractio	nal Efficie	ncy (%)		
0.3-0.4	67.4	74.9	76.3	78.6	85.4	89.3	67.4
0.4-0.55	81.6	86.9	87.5	89.6	94.6	95.5	81.6
0.55-0.7	90.9	94.0	94.8	95.4	97.5	98.6	90.9
0.7-1.0	96.6	97.5	98.2	99.1	99.5	99.9	96.6
1.0-1.3	98.7	99.0	99.4	99.7	99.9	100.0	98.7
1.3-1.6	99.4	99.5	99.8	99.9	100.0	100.0	99.4
1.6-2.2	99.7	99.8	99.9	100.0	100.0	100.0	99.7
2.2-3.0	99.8	100.0	100.0	100.0	100.0	100.0	99.8
3.0-4.0	99.9	100.0	100.0	100.0	100.0	100.0	99.9
4.0-5.5	100.0	100.0	100.0	100.0	100.0	100.0	100.0
5.5-7.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
7.0-10.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0



ENGINEERING APPROVAL K.C. KWOK, PH.D.____

LMS Technologies, Inc. 6423 Cecilia Circle, Bloomington, MN 55439 (952) 918-9060, Fax: (952) 918-9061

Date:

May 12, 2016

Test Requested by:

Filter ID:

Bair Hugger Filter-700 Series #1

3M

Test Type:

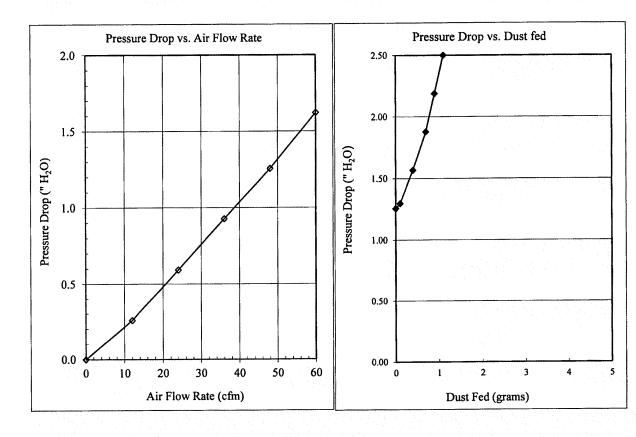
Pressure Drop of Clean Filter

Filter Manufacturer:

For ASHRAE 52.2-2012

REP# 3463 |3]

Flow Rate CFM	Velocity FPM	dP (mm H2O)	Pressure drop ("H2O)	% of Rated Airflow	Dust fed	Pressure drop
0	0	0.00	0.000	0%	0.00	1.256
12	62	6.52	0.257	25%	0.10	1.296
24	123	15.05	0.593	50%	0.40	1.567
36	185	23.56	0.928	75%	0.70	1.878
48	246	31.91	1.256	100%	0.90	2.189
60	308	41.15	1.620	125%	1.10	2.500



ENGINEERING APPROVAL K.C.KWOK PH.D.____